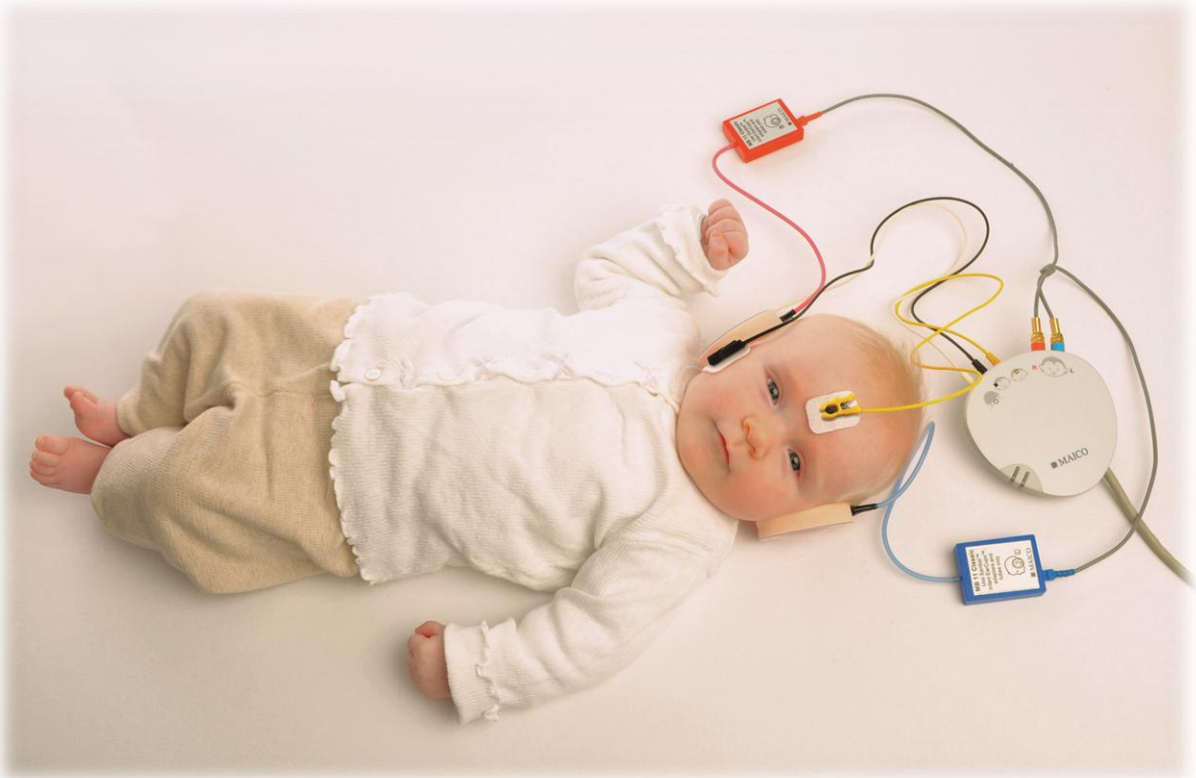
MAICO Diagnostic GmbH

Operating Instructions
MB 11 Classic



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Operating Instructions MB 11

Table of Contents **Page**

1 Introduction 3

2 Important safety instructions 4

3 Description 6

3.1 Auditory Brainstem Response (ABR) audiometry 6
3.2 The MB 11 Classic 6
3.3 Automatic Screening with the ASSR Algorithm 6

4 Installation and Settings 8

4.1 USB Specifications 8
4.2 Installation of MB 11 Software 8
4.3 Minimum computer specifications 8
4.3.1 Power supply 9
4.4 Operating system settings 9
4.4.1 Deactivate “save power” (USB hubs) 9
4.4.2 Change Power Options 13
4.4.3 Change visual effects 17
4.4.4 Change Display Properties 19
4.4.5 BIOS Setup 20

5 Getting started 21

5.1 Unpacking your instrument 21
5.2 Preparing the MB 11 for use 22
5.3 Device Recognition 23
5.4 Menus 24
5.4.1 Menu “File” 24
5.4.2 Menu “Settings” 25
5.4.3 Menu “About” 28
5.5 Operation with mouse and keyboard or touch-screen 29
5.6 Registry of new patient data 31
5.7 Loading stored patient data 32
5.8 Working with a “Today’s list” 33

6 Automatic testing in the automatic ABR screening mode 34

6.1 Preparing the Patient for measurements 34
6.2 Placement of the Electrodes 35
6.3 Placement of EarCups 35
6.3.1 Insert earphone tubing and adapters 35
6.3.2 Use of adhesive EarCup couplers 35
6.3.4 Removal of disposables 36
6.4 Performing the screening test 37
6.4.1 Impedance Test 39
6.4.2 The signal quality control 40
6.4.3 EEG-Display 41
6.4.4 Test result “Pass” 43

6.4.5 Test result "Refer" 44
6.5 Binaural Screening 45
6.5.1 Preparing for a Binaural Screening 46
6.5.2 Binaural Screening Result 46
7 Tracking 48
7.1 Tracking Settings 48
7.2 Input of Tracking data 49
7.3 Advanced Tracking data 50
7.4 The export functions of the MB 11 database (no tracking enabled) 50
7.5 The export functions of the MB 11 database (Tracking enabled) 51
8 Technical Data 52
9 Scientific Background Information 55
9.1 CE-Chirp Stimulus™ 55
10 Warranty, Maintenance and After-Sales Service 59
11 Safety Regulations 60

1 Introduction

Thank you for purchasing a quality product from the MAICO family. This automatic ABR-test system MAICO MB 11 Classic is manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive 93/42/EEC.

In designing the MAICO MB 11 we placed particular importance in making it a user-friendly device, meaning its operation is simple and easy to understand. And because all functions are software controlled, upgrading later to new, extended measurement functions will be simple and inexpensive. That means that you have invested in a device that will adjust to your future needs.

If you have problems or have ideas for further improvements, please get in touch with us. Simply call.

Your MAICO-team

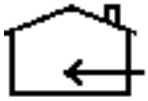
2 Important safety instructions

The MAICO MB 11 Classic is designed to be used only by skilled personnel (Audiologists, Physicians or other trained personnel). No person should attempt to use this instrument without the necessary knowledge and training to understand how this equipment is to be properly utilized and interpreted.

The MAICO MB 11 is intended for use on intact, external skin around the ears and on the scalp. It should not be used if the skin is not intact or if the baby has a contagious dermatological condition.

Electro-medical instructions with strong electromagnetic fields (e.g. microwaves - radiotherapy devices), can influence the function of the MB 11 Classic. Therefore the use of these instruments is not allowed in close proximity to the MB 11 Classic.

The test room must be at normal temperature, usually 15°C / 59°F to 35°C / 95° F. If the device has been cooled down (e.g. during transport), please wait until it has warmed up to room temperature.



The MAICO MB 11 classic is specified according to IEC 60601-1 safety against electrical hazard. This is only guaranteed, when the connected notebook computer is powered by batteries or the computers power supply accords to IEC 60601-1 or IEC 950-1 safety regulations and an isolation transformer meeting requirements of IEC 61558-2-1 or 60601-1 is used. The complete system must meet the leakage current requirements of IEC 60601-1-1. This complete system consisting of the MB 11 Classic, computer and isolation transformer, is suitable for use in the patient environment. Equipment not complying with IEC 60601 shall be kept outside the patient environment. Additional equipment not specified as part of the system shall not be connected.

Prevent cable breakage: The MB 11 Classic cables must not be bend or buckled.

Do not use the instrument if the mains cable and/or the outlet is damaged.

Patient safety: Place the patient at least 1.5 m away from Notebook or computer. Alternatively work in battery mode, use a Medical-PC or a special mains adapter according IEC 60601-1.

Precautions

READ THE ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS UNIT. Use this device only as described in this manual.

Before measurement make sure, that the device works properly.

Do not drop or cause undue impact to this device. If the instrument is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

Do not immerse the unit in any fluids. See the Cleaning section of this manual for proper cleaning procedures.

Use and store the instrument indoors only. Do not expose this instrument or its accessories to temperatures below 59°F (15°C) or above 95°F (35°C), or to relative humidity of more than 75%.

Do not attempt to open or service the instrument. Return the instrument to the manufacturer for all service. Opening the instrument case will void the warranty.

Disclaimer

The MAICO MB 11 Test Instrument is designed to be a screening device for hearing loss. Sensitivity and specificity of this type of device are based on the test parameters defined by the user, and may vary depending on environmental and operating conditions. The presence of normal evoked potentials suggests normal hearing.

However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a passing result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

A REFER test result should not be assumed to be an indicator of a lack of auditory function; however it should be followed with full audiologic diagnostic testing.

Use only Sanibel EarCups™. The device is only calibrated to this ear coupler. If other ear coupler or in-the-ear insert phones are used, the stimulus is not applied anymore with the correct level. No relibale results will be obtained!

3 Description

MB 11 tests hearing function by measuring the brainstem auditory evoked response of the auditory pathway. Processing of EEG samples allows the auditory brainstem response generated by the delivery of the acoustic stimulus and present in the EEG to be differentiated from generalized EEG activity.

3.1 Auditory Brainstem Response (ABR) audiometry

Brainstem potentials, BERA (brainstem evoked response audiometry) or ABR (auditory brainstem response), are optimally measured on a quiet, sleeping patient. In fact, sleep is conducive to improving the quality of the recording and reducing test time.

3.2 The MB 11 Classic

The MB 11 Classic uses standard disposable electrodes to record an auditory brainstem response (ABR). Sanibel EarCups™ are used to deliver the acoustic stimulus.

The MB 11 performs a fixed intensity (35 dB nHL) ABR screening. It is particularly suited for newborn hearing screening.

Figure 1
Testing with MB 11 Classic

3.3 Automatic Screening with the ASSR Algorithm

The acoustical CE-Chirp stimulus is presented at a high repetition rate (93/second). At this rate a so-called "**A**uditory **S**teady-**S**tate **R**esponse" (**ASSR**) occurs. The objective statistical determination of the presence of the ASSR is performed after the EEG is processed to determine its frequency content. The ASSR is described in the frequency domain by a few spectral lines (harmonics), mathematically related to the stimulus rate of about 93 Hz. The statistical test uses the phase and amplitude information of the harmonics below 1200 Hz. Frequencies in the processed EEG that are not related to the stimulus rate contain no response to the auditory stimulus, but only contain generalized EEG activity or "noise". These spectral lines will not be considered in the test result. This signal detection algorithm is associated with short test times as well as high immunity against distortion from electrical interference.

The detection algorithm enables simultaneous binaural measurements. The stimulus for the left and right ear is presented with slightly different repetition rates. The ASSR response of each ear have harmonics at different frequencies, those can be detected separately by the detection algorithm.

The statistical test is performed using repeated EEG samples of one second. The first test is done after passing the impedance test and then the test is repeated every second, until the overall test result arrives at critical value (the green marked PASS criteria, see figure 2). Then the test will be stopped with the test result "PASS". If the PASS criterion is not achieved after 180 seconds of artifact-free EEG sampling, the test is terminated with a "REFER" result.

Figure 2
MB 11 - program test result - "PASS"

Please see section 11 for additional scientific background on the stimulus and algorithm used with the MB 11 device.

Neither the algorithm nor critical test values are adjustable by the user.

4 Installation and Settings

4.1 USB Specifications

The MB 11 is a high-powered device that requires a USB port with 500 mA dc current over the VUSB - line. Passive USB hubs without an internal or separate power supply do not work with the MB 11 hardware. We recommend using a USB port directly on the PC or notebook computer. In most cases, these ports allow the use of high-powered functions / devices.

If you use additional USB devices on your PC and the MB 11 does not work or interferes with the function of simultaneously-used USB devices, try another USB port to change the USB hub output.

4.2 Installation of MB 11 Software

Boot the PC and wait until the operating system finishes the start-up process. Please note that the MB 11 is only supported by MS Windows 2000 SP4 and above and MS Windows XP SP1and above*, Windows 7 Professional and Windows 8 Pro. The following installation guide is based on the use of MS Windows XP. MS Vista is not supported.

Install the MB 11 Software with the USB driver files. Please note that you need administration rights for software installation. Install the MB 11 software before connecting the MB 11 to the USB port on the computer. After installation of the MB 11 software, connect the MB 11 to the USB port of your PC and check that the red LED on the MB 11 pre-amplifier® lights up.

If this LED does not light up, ensure that your USB port supports high-powered USB devices or change the USB port and try again. Also see 4.1 above about using USB ports. After a few seconds, the system will show a message about a newly found USB device “MAICO MB 11”. Allow the wizard to install the MB 11 driver if necessary.

4.3 Minimum computer specifications

Processor: Intel Pentium 800 MHz compatible or better
RAM: 256 MB
Hard disk: 2 GB
Interface: USB 1.1 or 2 (MB 11 requires a USB port with 500 mA dc current over the VUSB – line)
Display: SVGA (800x600)
Grounded power supply
Operating system: Windows XP SP 1 or later, Windows 2000 SP 4 or later, Windows 7 Professional or Windows 8 Pro.

4.3.1 Power supply

NOTE: The PC used with the MB 11 must either be grounded, or the laptop must be in used in battery mode.

Use only protective earth conductor plugs and wiring for the power supply. The lack of grounding will lead to enhanced humming noise with a large affect on the measurement quality. The buzzing noise also affects the audio output of computers and produces a masking noise signal. This will falsify the results of the measurements.

PC battery Mode:

To assure the most undisturbed (humming noise free) measurement and masking noise free stimuli, it is necessary to disconnect all external accessory PC devices, such as those with external power supply like USB Units, printers and local area network cables (LAN).

If it is necessary to use accessory devices while you operate in the battery mode, ensure a separate continuous and sufficient grounding of your PC.

4.4 Operating system settings

To get the best possible performance for the MB 11 Classic, it might be necessary to change the properties of the computer / notebook systems used. A description of these settings is provided below.

4.4.1 Deactivate “save power” (USB hubs)

Therefore select Run within the “START” column, type devmgmt.msc and confirm

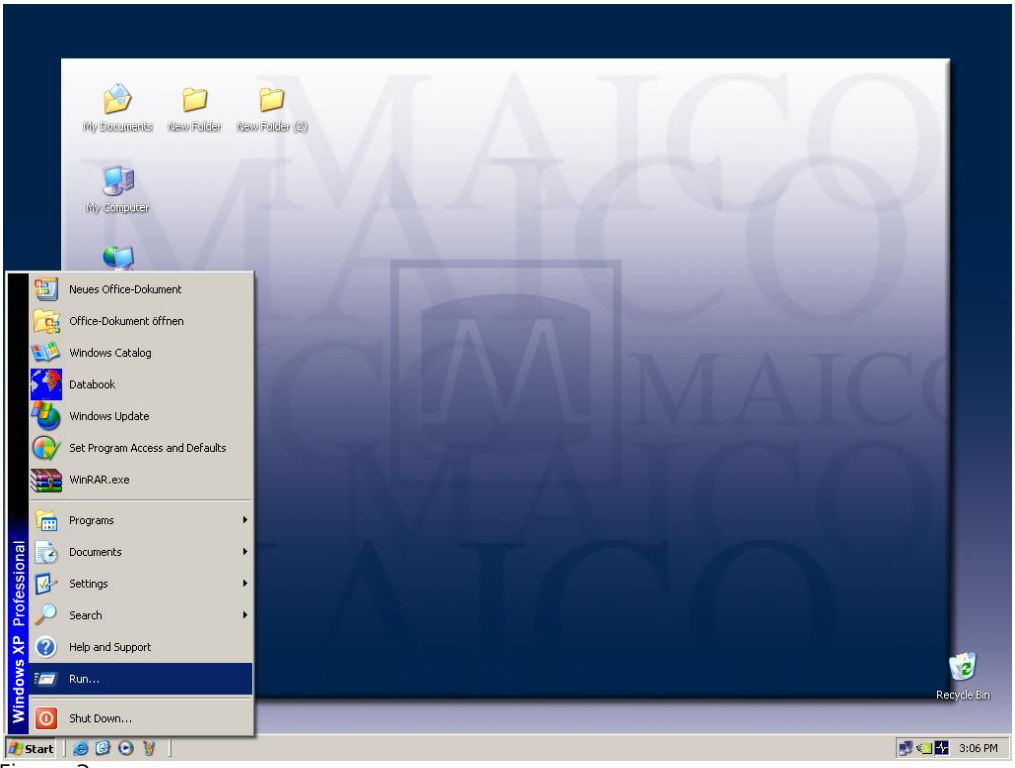


Figure 3

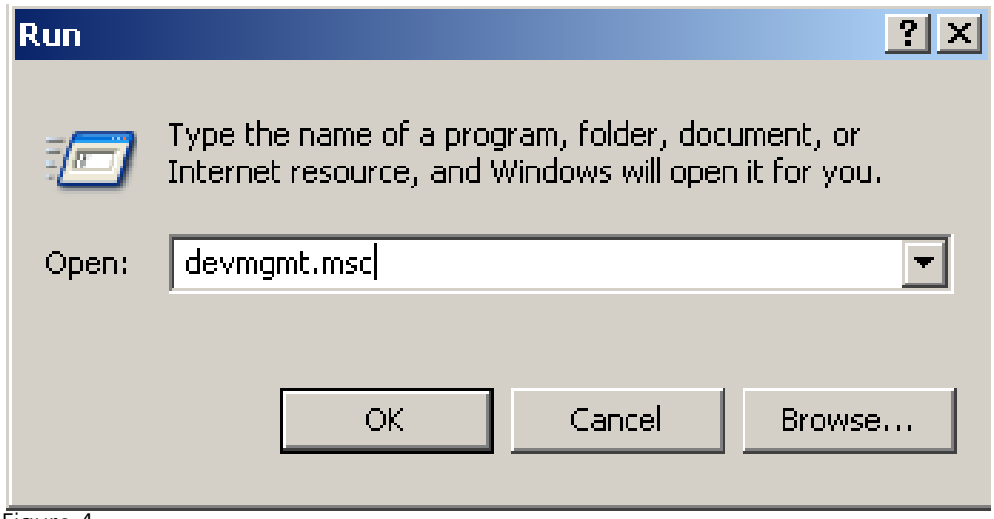


Figure 4

Select **Universal Serial Bus controllers** and then select a listed **USB Root Hub**. Double-click to open the Properties and select the Power Management tab of the Properties dialog. Remove the check mark if preselected. (Don't allow the computer to turn off this device to save power.)

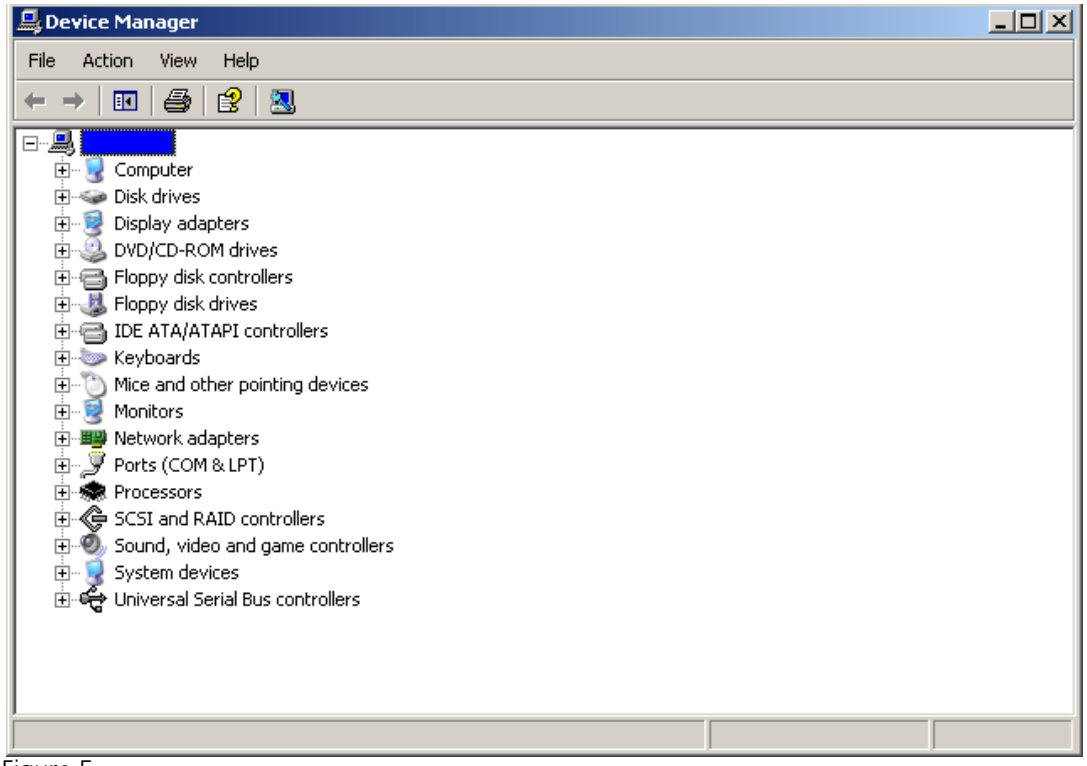


Figure 5

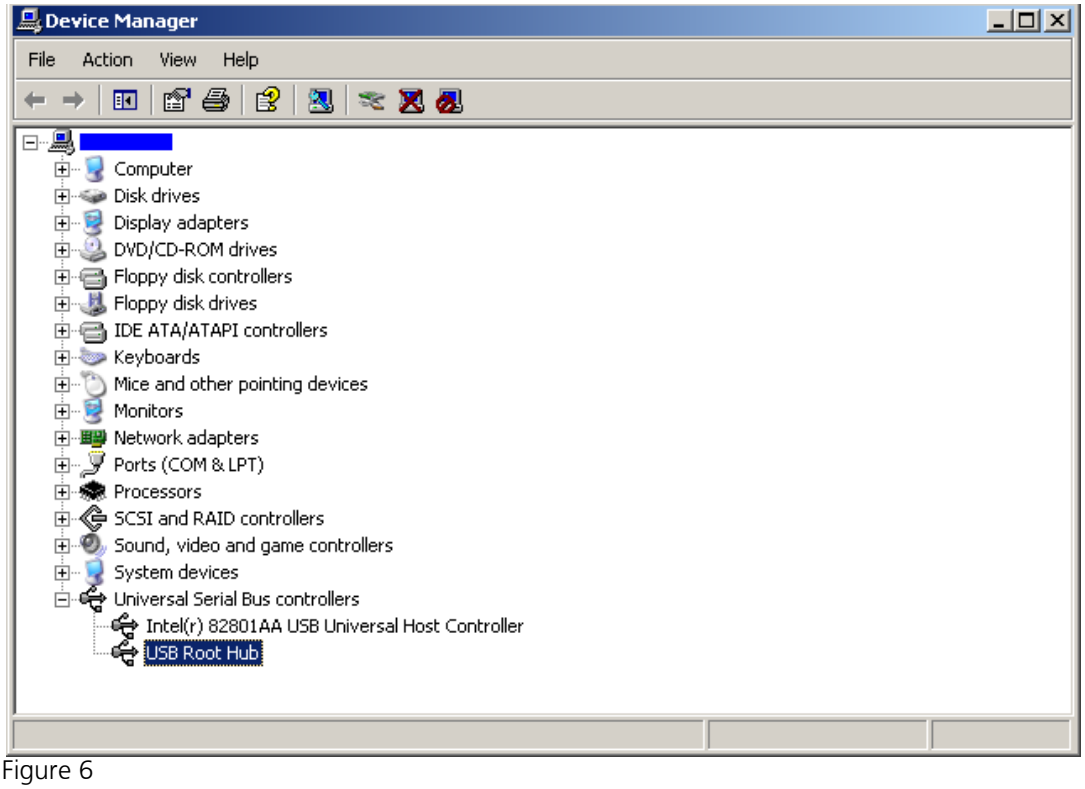


Figure 6

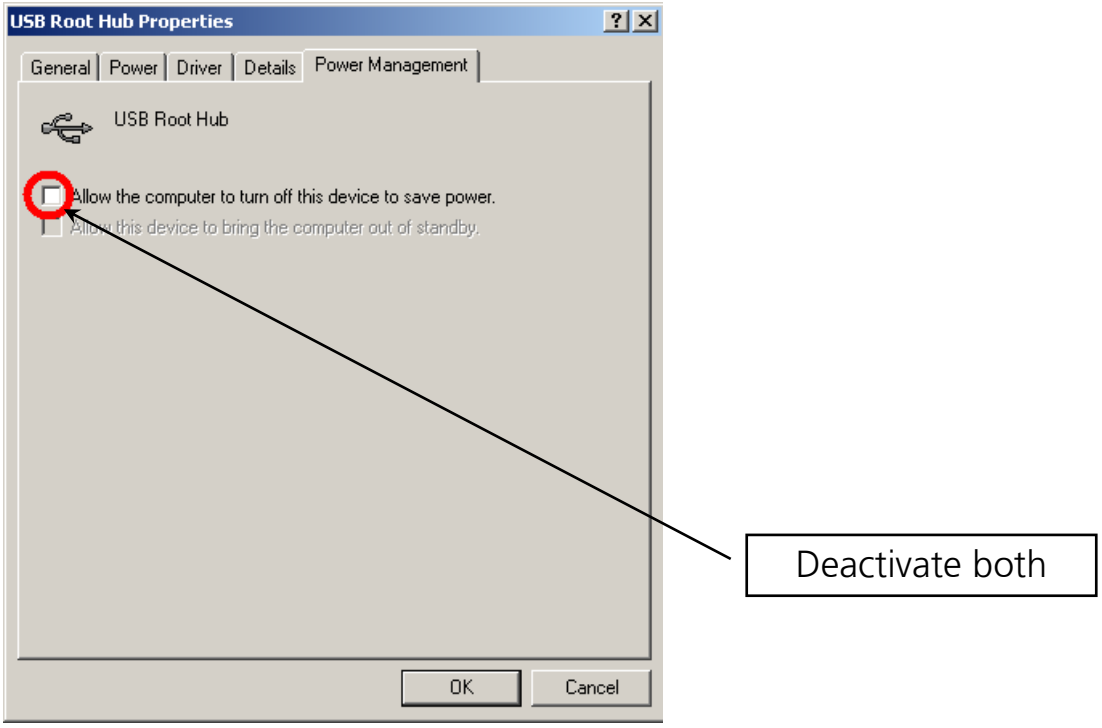


Figure 7

If there are more than one listed USB Root Hubs, please repeat the procedure as described above and take out the check mark if preselected for each of them. (Do not allow the computer to turn off this device to save power).

4.4.2 Change Power Options

To change power options select **Run** within the "START" column, type **powercfg.cpl** and confirm

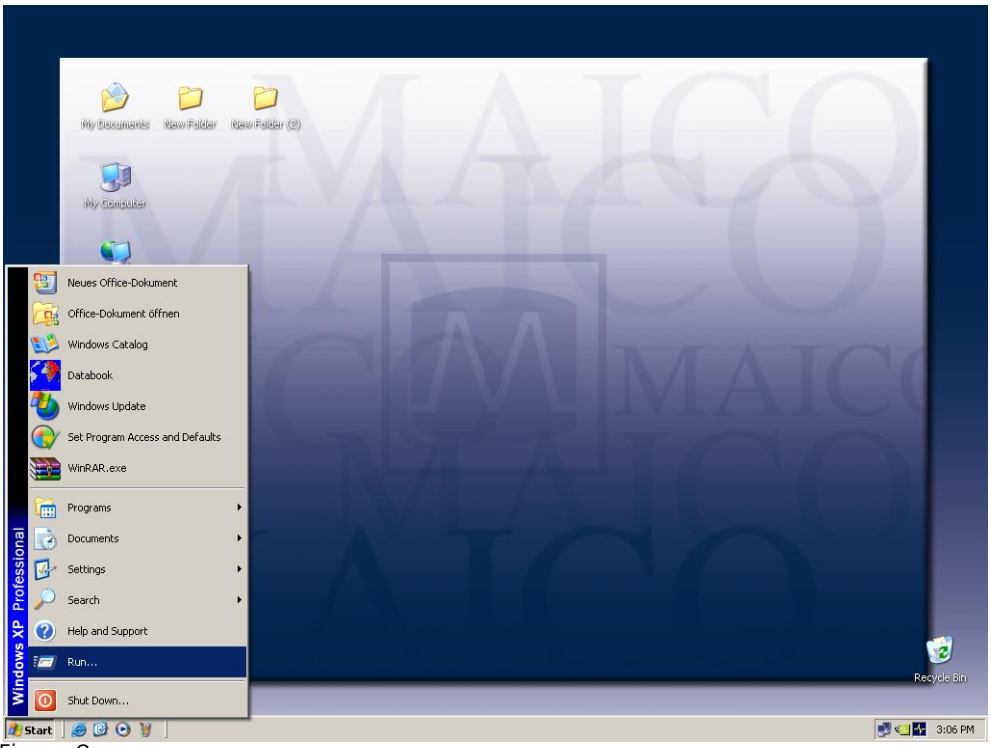


Figure 8

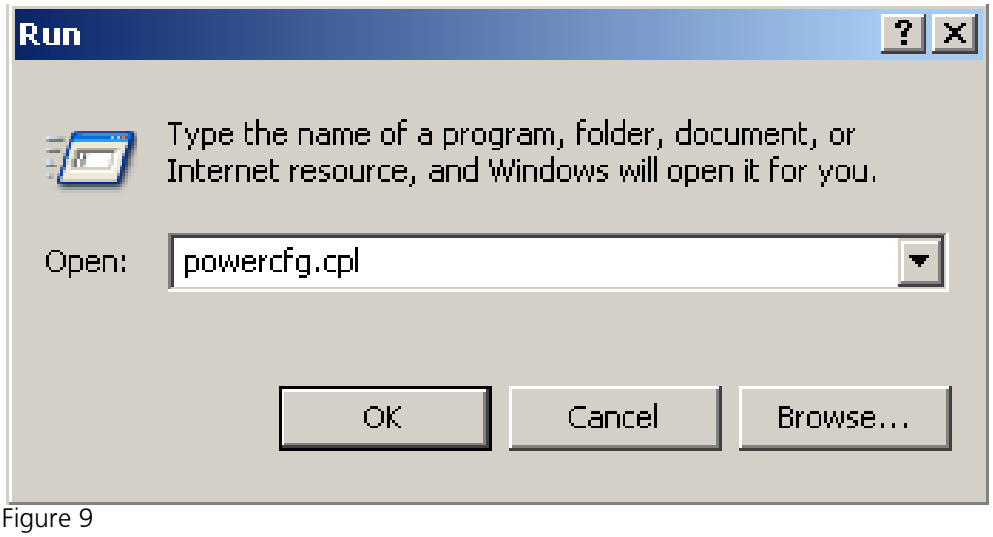


Figure 9

If you use a desktop computer select **Home/Office Desk** within the Power Schemes and select **never**:

Turn Off monitor: **never**
Turn off hard disk: **never**
System on standby: **never**

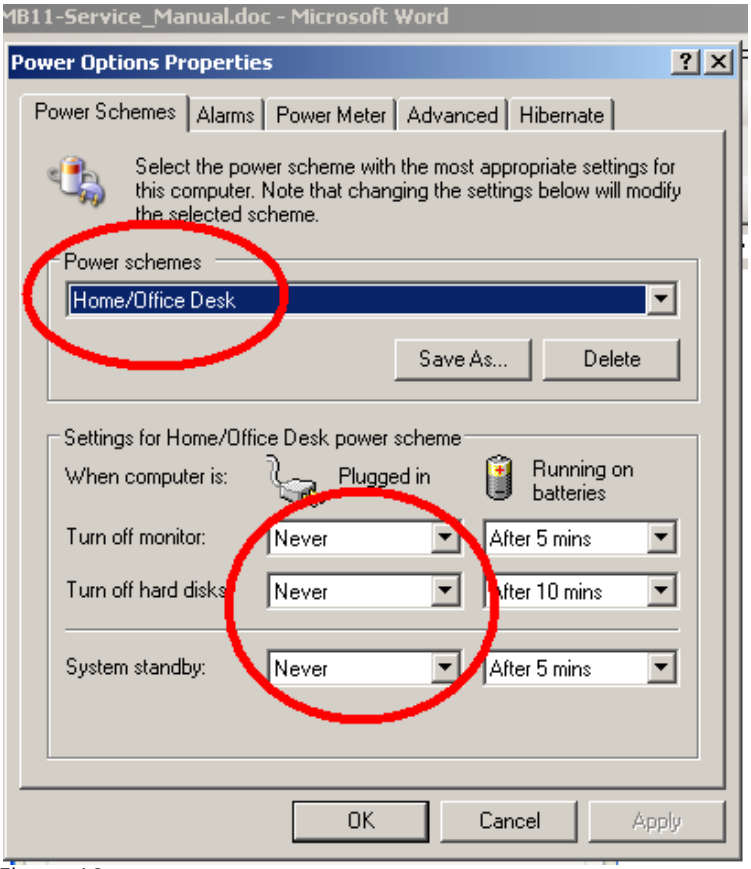


Figure 10

Select **Hibernate** within the menu bar and change Hibernate settings to off as shown in the picture.

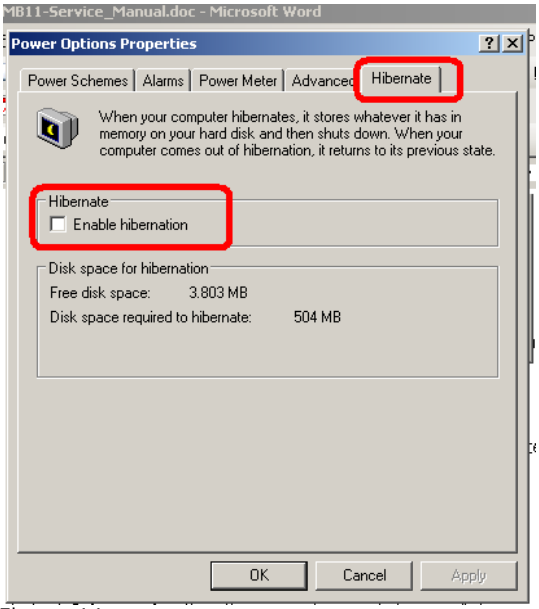

MB11-Service_Manual.doc - Microsoft Word
Power Options Properties
Power Schemes
Alarms
Power Meter
Advanced
Hibernate
When your computer hibernates, it stores whatever it has in memory on your hard disk and then shuts down. When your computer comes out of hibernation, it returns to its previous state.
Hibernate
Enable hibernation
Disk space for hibernation
Free disk space: 3.803 MB
Disk space required to hibernate: 504 MB
OK
Cancel
Apply

Figure 11

If you use a Notebook computer select **Portable/Laptop** within the Power Schemes and select **as follows**:

	Plugged in	Running on batteries
Turn off monitor	never	after 30min
Turn off hard disk	never	after 30min
System standby	never	never
System hibernates	never	never

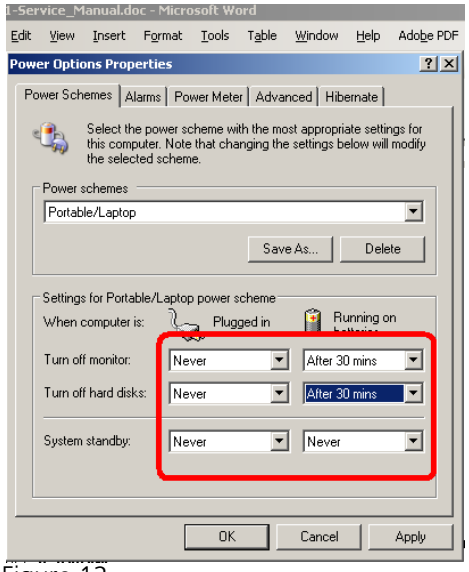


Figure 12

Select **Hibernate** within the menu bar and change Hibernate settings to off as shown in the picture.

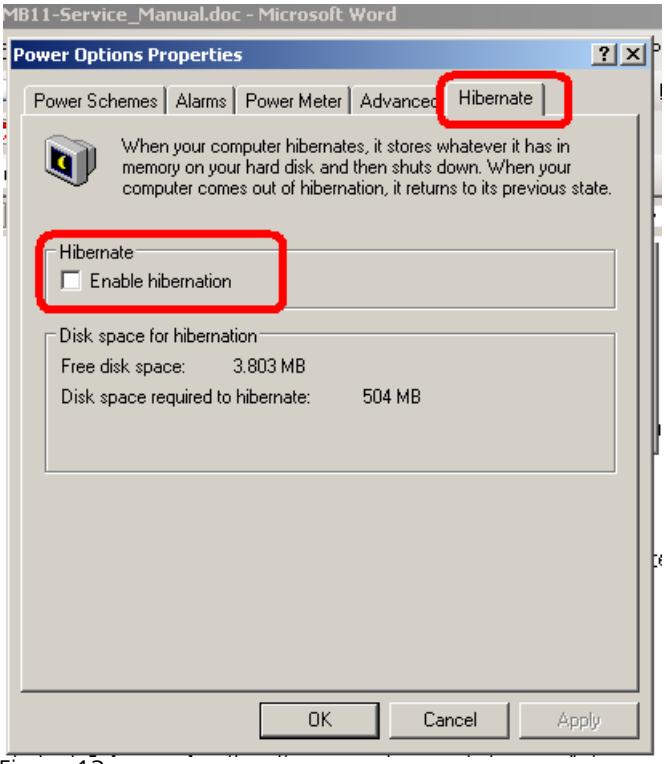

MB11-Service_Manual.doc - Microsoft Word
Power Options Properties
Power Schemes
Alarms
Power Meter
Advanced
Hibernate
When your computer hibernates, it stores whatever it has in memory on your hard disk and then shuts down. When your computer comes out of hibernation, it returns to its previous state.
Hibernate
Enable hibernation
Disk space for hibernation
Free disk space: 3.803 MB
Disk space required to hibernate: 504 MB
OK
Cancel
Apply

Figure 13

Select **Advanced** within the menu bar and change Advanced settings to "When I close the lid of my portable computer" **Do nothing** as shown in the picture.

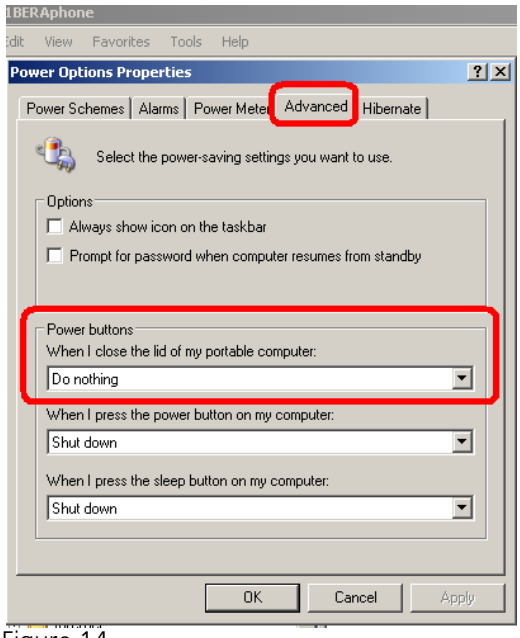


Figure 14

4.4.3 Change visual effects

(Optional at low-power PC)

To change visual effects select **Run** within the "START" column, type **sysdm.cpl** and confirm

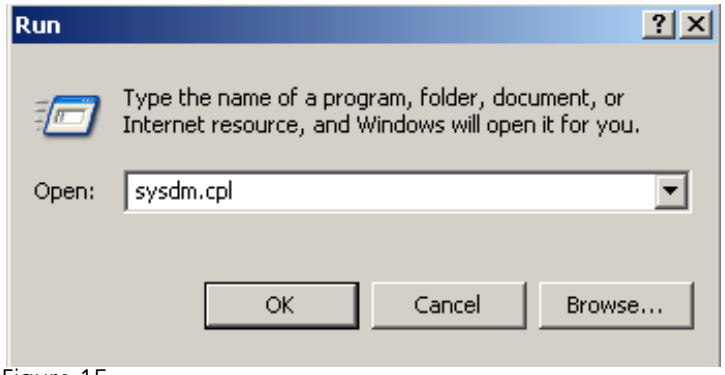


Figure 15

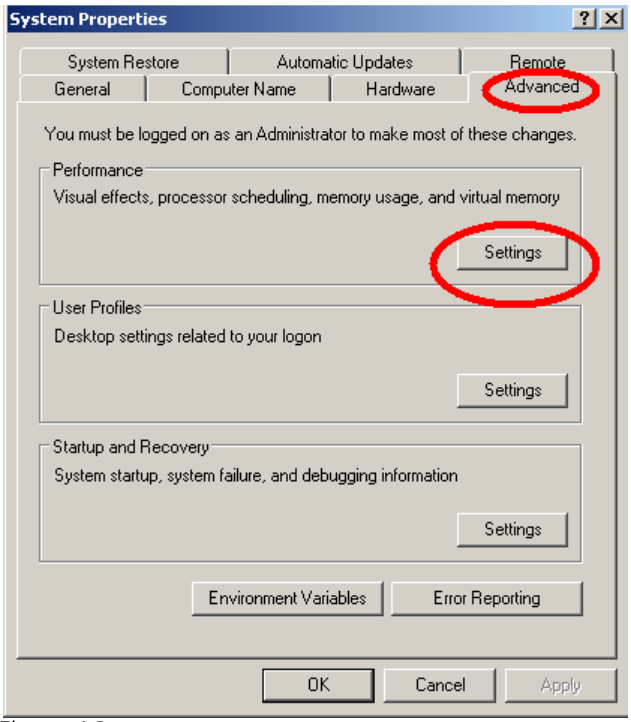
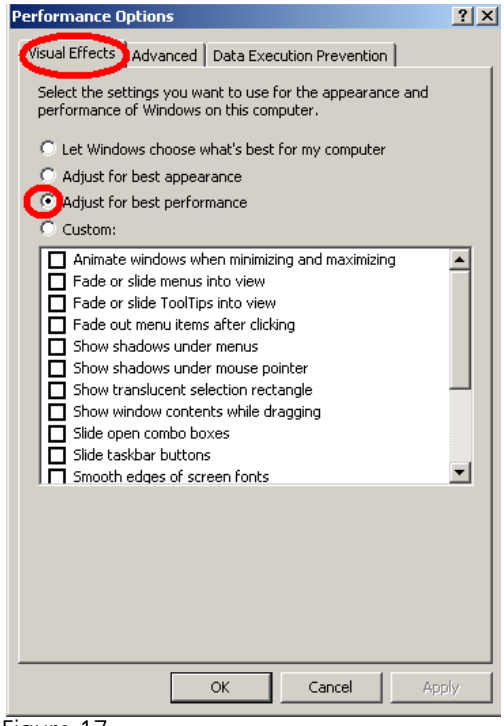


Figure 16


Performance Options
Visual Effects
Advanced
Data Execution Prevention
Select the settings you want to use for the appearance and performance of Windows on this computer.
Let Windows choose what's best for my computer
Adjust for best appearance
Adjust for best performance
Custom:
Animate windows when minimizing and maximizing
Fade or slide menus into view
Fade or slide ToolTips into view
Fade out menu items after clicking
Show shadows under menus
Show shadows under mouse pointer
Show translucent selection rectangle
Show window contents while dragging
Slide open combo boxes
Slide taskbar buttons
Smooth edges of screen fonts
OK
Cancel
Apply
Figure 17

4.4.4 Change Display Properties

(Optional at low-power PC)

To change display properties select **Run** within the "START" column, type **desk.cpl** and confirm.

Select **Desktop** and change background settings to **none.**

Select **Screen Saver** setting to **none.**

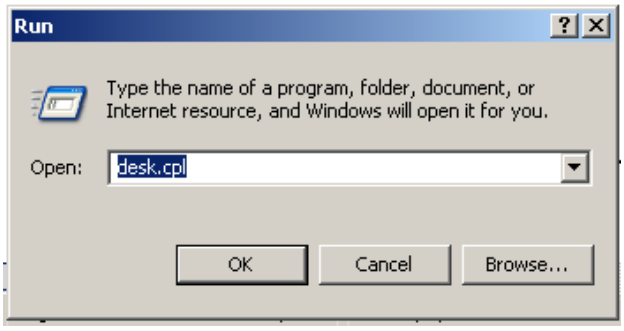


Figure 18

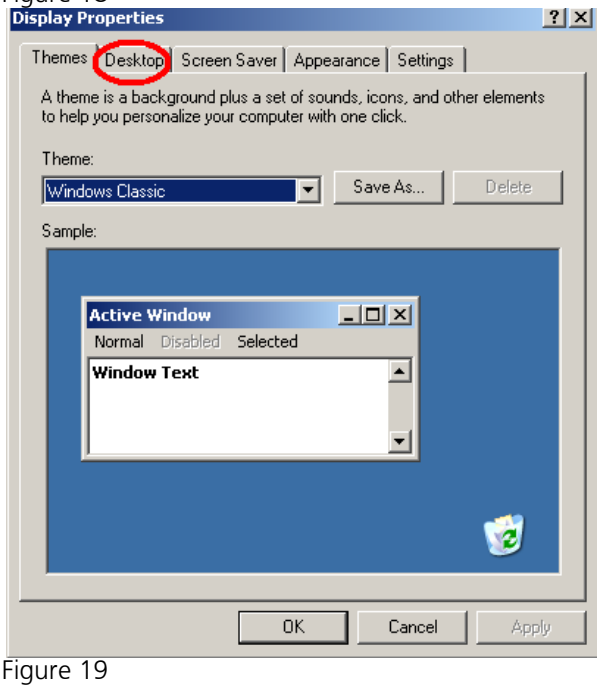


Figure 19

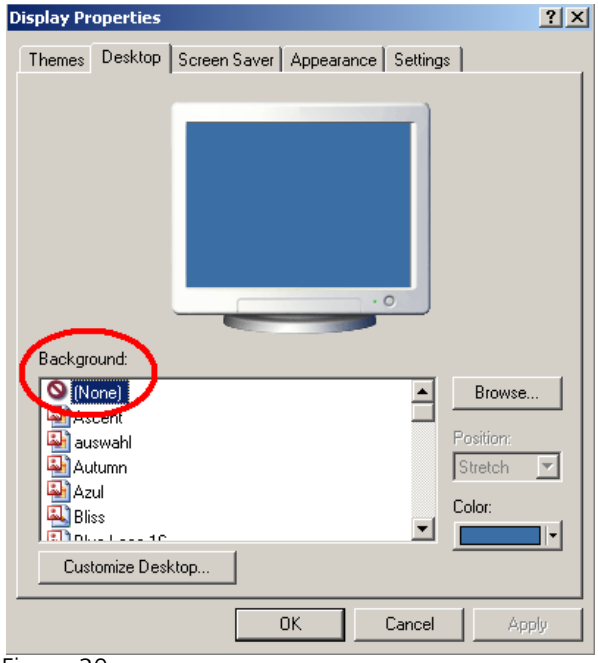


Figure 20

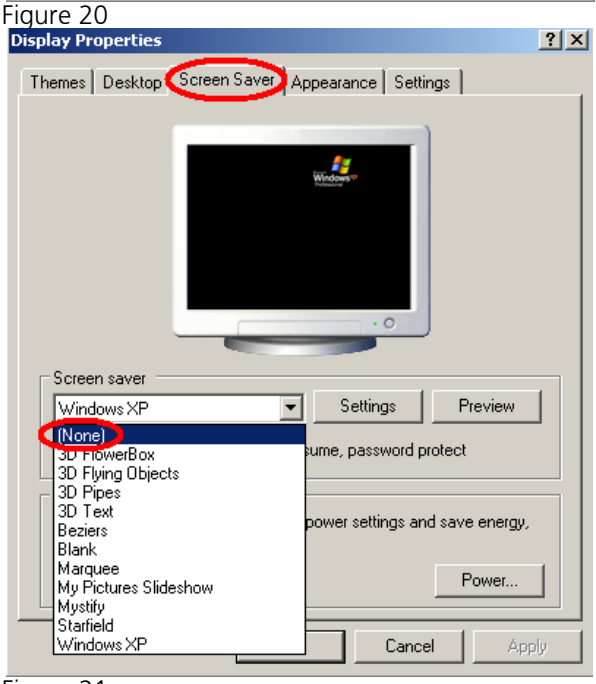


Figure 21

4.4.5 BIOS Setup

Because the MB 11 software uses real-time and processor-intensive algorithms, we recommend disabling energy saving processor settings in the BIOS, like “throttling” on Intel Pentium or “Power Now” on AMD Athlon.

For further details, consult the documentation for your main board or ask your local computer dealer.

Additionally it is recommended to adjust the value of system performance inside the system control to “optimal”.

5 Getting started

5.1 Unpacking your instrument

Your MB 11 Classic was carefully inspected and packed for shipping. However, it is good practice to thoroughly inspect the outside of the shipping box for signs of damage. Carefully remove the instrument from the shipping box. Remove the plastic bag from the instrument and inspect the case for any damage.

If any damage is noted, please notify the carrier immediately. This will assure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or MAICO when the adjuster has completed the inspection.

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

Please check that all accessories listed below are received in good condition. If any accessories are missing or damaged, immediately notify your dealer or MAICO.

Standard accessories – MB 11 Classic

- MB 11 Classic with pre-amplifier
- Box of Infant Ear-Cups and snap electrodes
- Electrode cable kit for snap electrode 3 pcs (Black, Yellow, White)
- ER-3A Insert Phones
- EarCup adapters (2 pcs)
- Nuprep® abrasive skin preparation gel
- USB cable
- Carrying bag
- USB drive with MB 11 software
- Operation Manual

5.2 Preparing the MB 11 for use

The MB 11 unit consists of a USB interface box connected with the MB 11 Classic preamplifier by a cable.

A USB cable connects the MB 11 interface box with a USB port of a mobile or desktop computer.

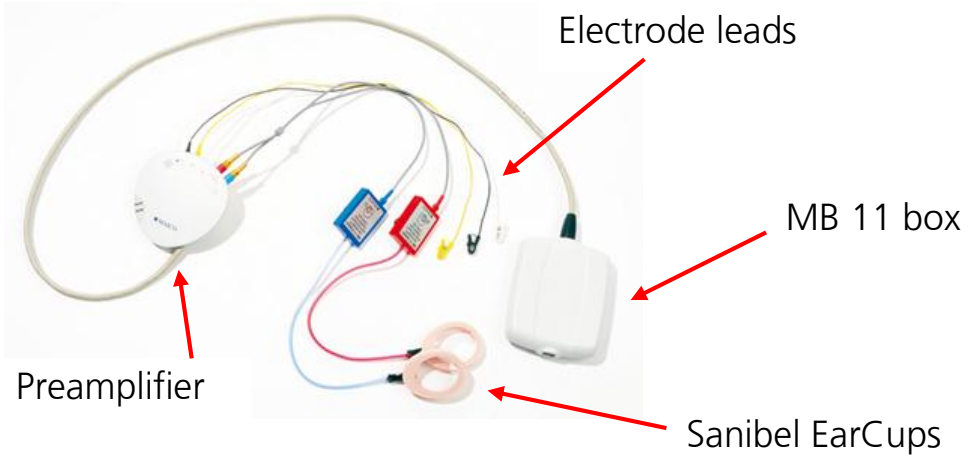


Figure 22
MB 11 Classic with electrodes and Sanibel EarCups

The MB 11´s power is directly supplied through the computer via the USB port. No external power supply is needed.

The insert earphones and electrode leads plug into jacks in the preamplifier (see Figure 22).

The MB 11, like any hearing screening device, should be operated in a quiet room, so that the screening results are not negatively influenced by outside acoustic noises.

Electro-medical instruments with strong electromagnetic fields (e.g. microwaves - radiotherapy devices), can influence the function of the MB 11 Classic. Therefore the use of these instruments in close proximity to the MB 11 Classic should be avoided.

The test room must be at normal temperature, usually 15°C / 59°F to 35°C / 95° F. If the device has been cooled down (e.g. during transport), please wait until it has warmed up to room temperature.

5.3 Device Recognition

You can connect multiple MB 11 devices to a single computer. When more than one MB 11 device is attached to the PC, a pop-up window displays the connected instruments when the software is launched. At that time you can choose the device you want to use with a mouse click. The most common scenario in which you would experience this pop-up window is if you have purchased a combination system including both the MB 11 BERAphone and the MB 11 Classic hardware.

To change between the BERAphone and the Classic hardware between screenings, after the software has been launched, press CTRL + U and the pop-up window opens allowing you to select your alternate hardware.

To close the program, just click on the "QUIT" <Q> button located on the bottom right of the screen. Additional functions are located in the Menu bar at the top of the screen. It contains the menus "File", "Settings" and "About".

After starting the computer, launch the MB 11 software by clicking the shortcut icon "MB 11 USB Version" on the desktop or direct from the program menu.

The program launches with the start screen (see Figure 23).

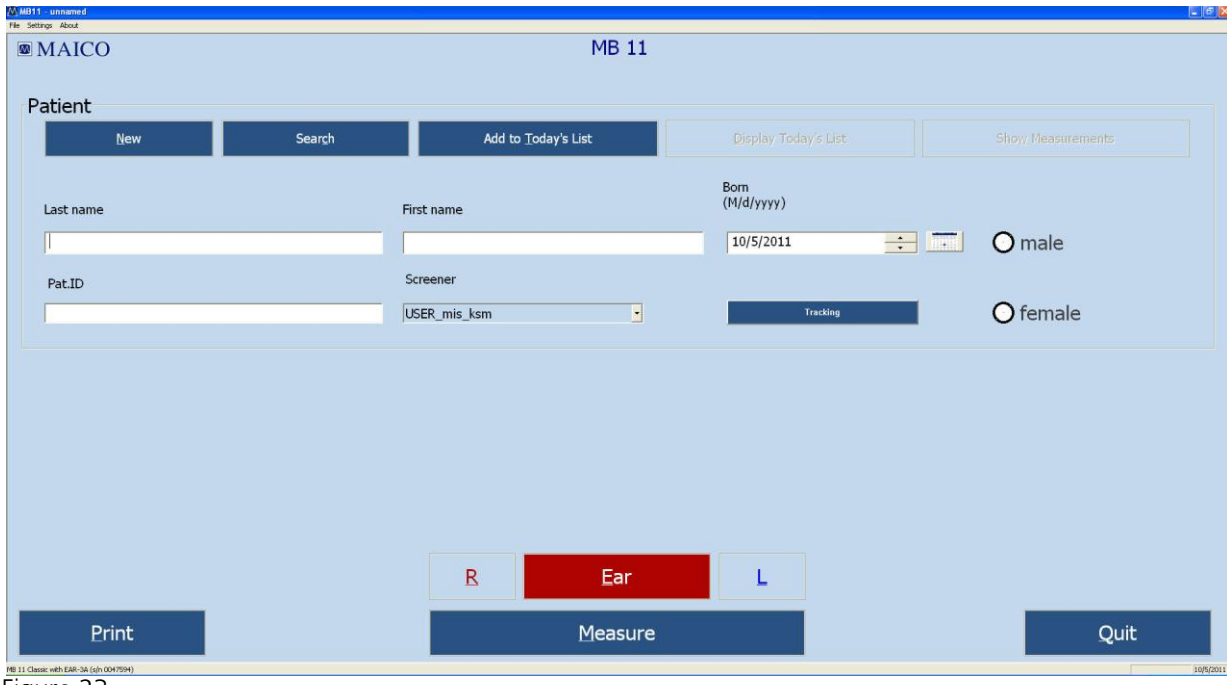


Figure 23
Start screen of the MB 11 program

5.4 Menus

5.4.1 Menu "File"

Figure 24
File Menu

"New" – Entry of a new patient (see also Tracking – Patient data). Clears all fields if they contain information on a previously tested patient.

"Search" - Launches a dialogue that allows selection of a patient from the integrated database. In this window, a patient can be selected by clicking the patient's name with the mouse. Various means are provided to filter the patient database so that fewer names appear in the list. After clicking on the desired patient, the patient's information appears in the fields of the start screen.

Data Filter options in the Search dialog include:

"Last Name Filter": Entry of a last name will filter the database to show only those with a matching last name.

Range of date filter: Use of the drop down allows you to filter the database for baby's screened within a certain time period (all data, data from today, data from last 3 days, data from last 7 days, data from last 30 days, data from the past year.) The computer's current date and test dates for the patients are used to make this determination.

Test Result filter: Use of the drop down allows you to filter the database for screening test outcomes (Pass, Refer, Abort, Not Measured). This filter will limit the names of the babies displayed in the list to those that have a test in the database that matches the displayed outcome. This filter does not filter for the last or "best" test result. In other words, a baby that ultimately passed a screening but at some point had a Refer result will be displayed in the list when the "Refer" filter is enabled.

Examiner/Screener Name filter: Use of this drop down allows you to filter the database for babies screened by a specific screener.

Number of cases field: This read-only field displays a count of the number of babies in the database that match the data filtering definitions.

Data export function: The Data Export controls allow you to set a data range using calendar controls and export patients and tests performed in this date range to a file that can be read in a spreadsheet program such as MS Excel. A Windows browser will appear to allow you to define the path and filename to which the data will be saved. This file can be opened for viewing using a text editor or a spreadsheet application. Information

contained in the .txt file includes: ID No. (as entered by the user), Name (last), First name, Sex, Birthdate (Born), Date of test (date and time), Screener, Ear (side), Test type (Mode), Result (Note).If additional fields are completed using the Hi*Track tracking feature, these fields are not exported through this function. In a spreadsheet this file should be viewed as a comma delimited file structure.

Tracking export function: The Tracking Export controls allow you to set a data range using calendar controls and export patients and tests performed in this date range to a file that is formatted according to the selection of either OZ or HiTrack set in the Options dialog. A Windows browser will appear to allow you to define the path and filename to which the data will be saved. This file can be merged into HiTrack or OZ. You must have purchased these third party databases from HiTrack or OZ and you must follow their procedures for merging the data in these export files into their databases.

"Print" – The function implemented by selection of the Print item depends on which "Print Mode" setting is enabled in the Options dialog.

"Quit" – Exits the MB 11 program.

5.4.2 Menu "Settings"

"Save Test settings" – Saves configurable test settings as user-selected defaults. Menu item is only available for selection from within the Measurement screen.

Figure 25
Settings Menu

"Reset settings to default" –

Resets configurable test settings to the original defaults. Menu item is only available for selection from within the Measurement screen.

"Options" (Figure 25) – This dialog allows you to define a number of user-selectable settings. The item is only selectable from within the Main screen.

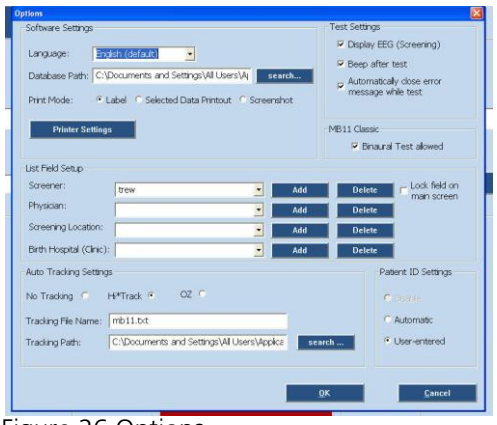


Figure 26 Options

The fields in the Software Settings area include:

"Language" - The program language can be changed to any of the available languages that are supported by the fonts installed on your PC.

"Database Path" – The path for the saving of the MB 11 database can be defined in this field. The MB 11 database file includes all patient and test information as well as

screener, physician, screening location and birth hospital entries entered in the List Field Setup area.

"Print Mode" – This allows the type of printout to be selected.

Enable **"Label"** to print to a supported label printer. In this mode, the "best" result for both ears will print out by default even if it is not the most current one performed. If there is no Pass result for one or both ears, then the most current Refer and then Aborted test will print. Use the "Selected Data Printout" setting to override this default printing scheme and choose your desired screening tests for printing to the label printer.

Enable **"Selected Data Printout"** to choose from a list of results for the current patient and print these results. These results can be printed to either a standard printer or to a label printer. When using a standard printer the results will print in lines on one print out. When printing to a label printer, each selected test will print out on an individual label.

Enable **"Screenshot Printout"** if you wish to print the graphical display of the final result for a chosen screening test. This is the same view of the measurement screen that you see at the conclusion of a screening. (It does not print an ABR waveform.)

"Printer Settings" – This control opens a standard Windows printer dialog from within the MB 11 software. For efficiency it is recommended that you set the typical printer you will use to print your MB 11 results as the default printer in the operating system settings.

"Encode Export Data" – If this option is enabled, all tracking files will be encrypted during export. In order to make sure that exported data can't be read or manipulated by any unauthorized person. A password is required to enable or disable this option. The exported text file can be decrypted by a separate decoder tool. Usually this is done at the tracking centre, where the exported file is send to. A description how to decrypt the tracking file and the password to enable or disable this option is only provided to an authorized person on demand.

The **List Field Setup** area allows you to add and delete names from the drop down fields. Use the Add control to add new names to the drop down list. Use the Delete control to remove the displayed name from the drop down field.

"Examiner/Screener" – a default name is present based on the PC name. Names added to the Examiner/Screener drop down list field will be accessible in the main screen. The key combination of Ctrl+E locks and unlocks the screener field on the main screen. When locked, then the screener field is ghosted with the default name displayed and cannot be changed. When entering these names to be used with merging data to

HiTrack, they must be entered in exactly the same format as they are entered in the HiTrack application or there will be merge errors upon importing the tracking file into HiTrack.

"Physician" – this is a HiTrack field. The list of physicians is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the "Tracking" control on the main screen. When entering these names to be used with merging data to HiTrack, they must be entered in exactly the same format as they are entered in the HiTrack application or there will be merge errors upon importing the tracking file into HiTrack.

"Screening location" – this is a HiTrack field. The list of screening locations is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the "Tracking" control on the main screen.

"Birth Hospital" – this is a HiTrack field. The list of hospitals is accessible for selection when HiTrack is enabled and when the user enters the Tracking dialog by selecting the "Tracking" control on the main screen. It is referred to as the Hospital code in the Tracking window.

The **Auto Track Settings** area allows you to set your tracking preference.

"No tracking" – no tracking file will be saved.

"HiTrack" – during collection a file will be continuously saved and appended to with each screening test. This file will be in the format required by the HiTrack third party database which the customer must purchase from the HiTrack provider. This setting also impacts the Tracking export function that is accessed in the Search dialog. So there are two ways to create a HiTrack tracking file. One occurs automatically when the HiTrack tracking function is enabled. One is performed through a manual process by exporting based on a manually entered date range entered in the Search dialog Tracking Export area.

"OZ" – during collection a file will be continuously saved and appended to with each screening test. This file will be in the format required by the OZ third party database which the customer must purchase from OZ. This setting also impacts the Tracking export function that is accessed in the Search dialog. So there are two ways to create an OZ tracking file. One occurs automatically when the OZ tracking function is enabled. One is performed through a manual process by exporting based on a manually entered date range entered in the Search dialog Tracking Export area.

"Tracking File Name" – Allows the user to define the desired name for the tracking file that is saved automatically during data collection.

"Tracking Path" – Allows the user to define the desired data path for saving of the automatically created tracking file.

The **Test Settings** area allows the user to enable (checked) or disable (unchecked) the following features that occur during a measurement:

"Display EEG (Screening)" – sets the EEG view as the default when enabled; otherwise the quality indicator bar is displayed above the measurement graphic during data collection.

"Beep after test" – enables an audible "beep" that occurs when a measurement is complete. The quality and audibility of the beep may be affected by the specific PC that is used.

"Automatically close test distortion message" – enabling of this control causes a pop up message regarding test distortion to disappear after 7 seconds. When disabled, the user must manually close this message that occurs immediately after an impedance test when cyclical noise is detected in the EEG signal.

The **MB 11 Classic** area allows the user to set preferences related to testing when the hardware being used is the MB 11 Classic rather than the BERAphone. This control will only show up in the dialog if an MB 11 Classic is attached to the PC when the software is launched.

"Binaural test allowed" – Enabling this setting allows access to a "binaural" test option during data collection with the MB 11 Classic. If this control is disabled, then only the right ear or left ear can be selected and only a monaural test can be performed.

The **Patient ID Settings** area allows the user to set preferences regarding the handling of the patient ID.

"Disable" – disables the field for the patient ID. Control is not available when Tracking is enabled. Disabling the Patient ID field allows you to collect and save test data without entering a patient ID. Disabling the patient ID can make it difficult to differentiate patients with the same name.

"Automatic" – disables the Patient ID field for user entry, but automatically assigns a random ID number upon entry of a new patient.

"User-entered" – the default setting; requires user to enter an ID for each patient.

5.4.3 Menu "About"

Click on "**About**" to see product information about the software version and contact information.

5.5 Operation with mouse and keyboard or touch-screen

The MB 11 program can be operated with the mouse by pointing and clicking on the required input field or button on the screen.

It is also possible to jump with the <TAB> key from field to field. Pressing the Enter key activates the selected field or button.

If you use a touch-screen you can run the program by touching the appropriate field on the screen.

Keyboard short cuts can also be used for fast operation. Press the <ALT> key together with the underlined letter of the required button. i.e. to start the measurement press the keys <ALT> and <M> together.

Keyboard short cuts:

Alt+F	File
Alt+S	Settings
Alt+A	About
Alt+N	New
Alt+C	Search (Load from Database)
Alt+T	Add to Today's list
Alt+R	Right Ear
Alt+L	Left Ear
Alt+E	Change Ear
Alt+D	Display Today's list
Alt+M	Start Measurement
Alt+S	Stop Measurement
Alt+Q	Quit
Alt+W	Show Measurements
Alt+P	Print
Ctrl+U	USB (Pop-up window with the connected MB 11devices)
Ctrl+B	Beep at the end of the measurement
Ctrl+E	Open/close the screener field
Ctrl+W	Automatic closing of test distortion message

There are also several shortcuts accessible by using the Function keys:

F1	Help
F2	Add to Today's List
F3	Display Today's List
F4	Ear/Other Ear
F5	Measure/Start Measurement
F6	Advanced Display On/Off
F7	Pause (Continue)
F8	Stop Measurement
F9	Print
F10	Quit
F11	Beep (at end of test) On/Off

5.6 Registry of new patient data

Figure 27 - MB 11 - program start screen with patient data

For a fast screening test without tracking, it is sufficient to enter the last and first name, birthday, gender and Patient-ID. If you do not enter this information, but continue with collection anyway, the patient and tests performed will not be saved in the database.

Tracking may require more detailed data. (Read more in Chapter 7 Tracking).

Enter the surname and first name of the patient/baby with the keyboard. Move between the different entry fields using the <tab> key or a mouse click in the required data field. The current PC date is displayed as the default value for the date of birth. Use the calendar control to modify the birthdate. Mark the sex of the patient by clicking the male or female radio button. The <Del> key can be used to delete the default setting prior to entering a different value.

Additionally you can load stored patient data (see chapter 5.7) or create a "today's list" of the patients to be tested today (see chapter 5.8).

Select the ear to be tested, < R > for right or < L > left, using the Ear button or the R/L buttons located just above the "Measure" button.

Now you are ready for testing. The test procedure is described in chapter 6.

5.7 Loading stored patient data

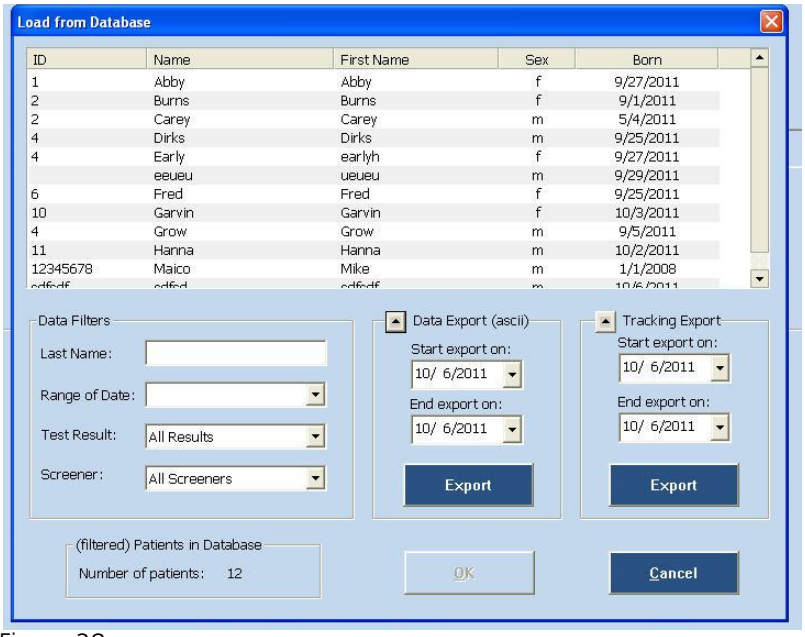


Figure 28
Load from database

After clicking on the button "Search", all stored patients will be shown (see Figure 28).

Select a patient by double-clicking on the name with the mouse or highlight the desired name and select the OK button.

If a test result already exists for this patient, the button "Show Measurements" on the right of the screen (see Figure 30) becomes active. By clicking on this button you can view a list of all tests performed on this patient and review each test result.

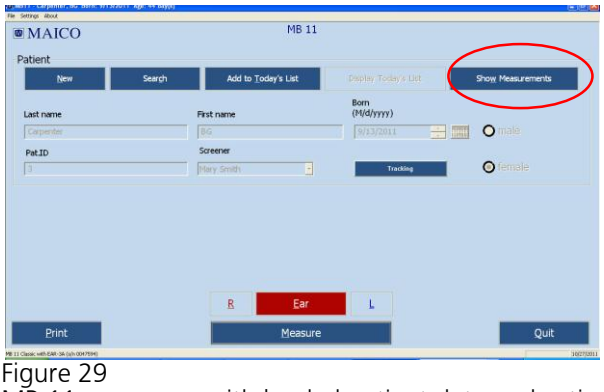


Figure 29
MB 11 - program with loaded patient data and active "Show Measurement" button

5.8 Working with a “Today’s list”

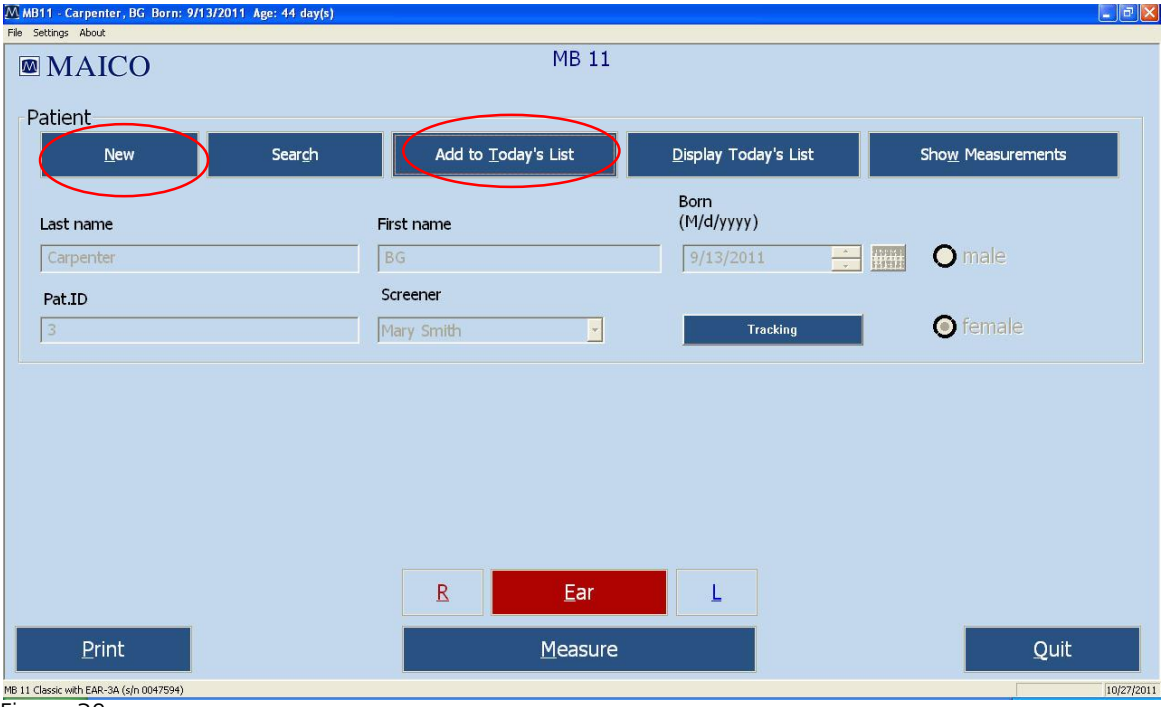


Figure 30
MB 11 - Today’s list

If several tests will be conducted in one day, it may be easier to enter the data of all babies before you start to test. In this case click on the button "New data" and enter the name, birthdate, ID and sex, as described in chapter 5.6. If you are saving additional information for HiTrack, click on the Tracking button and enter this additional data as well. After all the desired data is entered click on the button “Add to Today’s list”.

Now click again on the button "New data" and proceed as described before. Repeat this until you have entered the data of all babies to be tested.

Later on, when testing, you just have to click the button “Display Today’s list”. The list of the babies to be tested today appears on the screen so that you can select the desired name.

After selecting the baby to be tested, select the ear to be tested, right R or left L (or Binaural), and start the test by clicking on the button "Measure". For the test procedure refer to chapter 6.

Names entered into Today’s List will remain until at least one test has been initiated on the patient or until 48 hours have elapsed.

6 Automatic testing in the automatic ABR screening mode

It is fast and easy to screen patients with the built-in patented automatic Fast Steady State Algorithm. At the conclusion of the test or when the test is manually terminated, one of the following results will display and be saved with the screening.

Test Result Definitions

PASS: As soon as the indication mark reaches the green area (has met the Pass criteria), the result is "PASS". For binaural measurements a "PASS" is only displayed if both ears passed the test.

REFER: If no response at the test level of 35 dB nHL is present after 180 seconds of data collection, the test is automatically terminated with a "REFER" result. In this case, follow your screening program protocol to determine whether another screening should be performed or whether the baby will be referred for a diagnostic follow-up test.

ABORT: If the test is aborted ("Stop Measurement" is pressed during the test), the test is labeled as "ABORT". If any tracking is enabled, then a pop-up window appears for selection of a reason for stopping the test.

6.1 Preparing the Patient for measurements

Optimal ABR recording requires low skin-electrode resistance (electrode impedance).

To achieve low electrode impedance, the skin in the location where the disposable electrodes will be applied must be cleaned with an electrode skin preparation product. After cleaning, the residue of this cleaning product should be wiped away so that the skin is dry to promote optimal adhesion of the electrode to the skin.

Electrodes will be placed on three locations on the patient's head, i.e. the center of the forehead at the hairline, the side of the forehead near the temple (or, alternatively, on the cheek) and the nape of the neck.

The adhesive EarCups, around-the-ear couplers, need to be used with the insert earphones to deliver the acoustic stimulus.

The patient should be made as comfortable and relaxed as possible to minimize any potential muscle artifacts and ensure optimum test outcome in the shortest time.

Make sure that the face, neck and shoulder of the patient are relaxed.

6.2 Placement of the Electrodes

For electrode placement, the skin should be cleaned with an electrode skin preparation product to remove any oil and dirt from the skin's surface. Using a cotton-tipped applicator or your finger, rub the skin briskly but gently several times with the product. This will help to reduce skin impedance and ensure proper recording conditions.

After skin preparation, use a tissue to wipe away any residue of the skin prep product and to dry the skin.

Then, with the electrode cables already snapped/clipped onto the disposable electrodes, apply an adhesive electrode on each of the three electrode placement points, the high forehead, temple (or cheek) and nape of the neck.

6.3 Placement of EarCups

IMPORTANT NOTES

Insert earphones can be used only with EarCups that adhere to the skin around the ear. The EarCup adapter need to be attached at the end of the insert earphone tubing to connect them properly to the EarCups. Changing to in-the-ear insert phones or other disposables without proper calibration of your device will result in inaccurate test results due to calibration differences needed for different disposables.

There is a RIGHT ear and a LEFT ear insert earphone. It is important that you match the insert earphone to the correct ear for the results to be assigned to the proper ear in the database. For the right ear the red insert phone tube is used and for the left ear the blue one.

6.3.1 Insert earphone tubing and adapters

Verify that the tubing and adapter installed onto the insert phones correspond to the EarCup disposables.

6.3.2 Use of adhesive EarCup couplers

To apply the stimulus to the babies ear, adhesive EarCups that surround the baby's ear, are used. Remove the card with the EarCups from the package. Peel the EarCup off of the backing card and place it around the baby's ear with the opening for the insert phone tube adapters positioned at the top of the baby's ear. Gently apply pressure around the circumference of the EarCup to adhere the EarCup to the baby's skin. Repeat this process with the second EarCup placed on the other ear. Insert the insert phone tube adapters into each of the EarCups.

Be sure that the EarCup attached to the Right insert earphone (red) is applied to the right ear. Be sure that the EarCup attached to the Left insert earphone (blue) is applied to the left ear.

Make sure that the opening of the insert phone tube adapters are not blocked by the baby's ear and the insert phone tubes are not bended. Otherwise the stimulus is not presented properly to the ear. This can cause in wrong measurement results.

6.3.4 Removal of disposables

After the screening, the electrodes and ear tips or EarCups should be removed from the patient and discarded. These disposables are intended for single-patient use only. Removal of the electrodes and EarCups may cause some temporary discomfort to the patient.

6.4 Performing the screening test

Figure 31
MB 11 - program start screen

Enter or load patient data.

Prepare the patient and as described in chapter 6.1 and place the electrodes as described in chapter 6.2. attach the adhesive EarCups 6.3.

Select the ear to be tested. To perform a simultaneous binaural test, select the "Ear" button until it displays the word "Binaural" and the color of the button turn pink. If the Binaural ear choice does not display, check the "Binaural Test Allowed" setting in the Options menu to make sure that binaural testing is enabled.

Next click on "Measure": The measurement screen opens (see Figure 31).

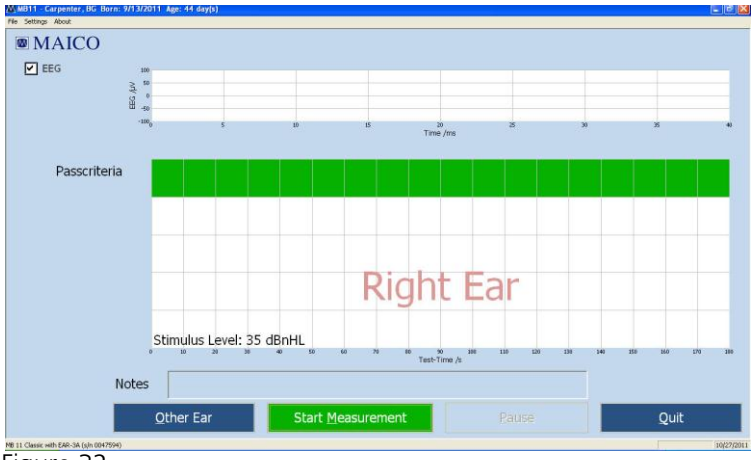


Figure 32
Start measurement

Start the test by clicking on "Start Measurement" button.

Before the measurement is started an automatic impedance test is performed.

6.4.1 Impedance Test

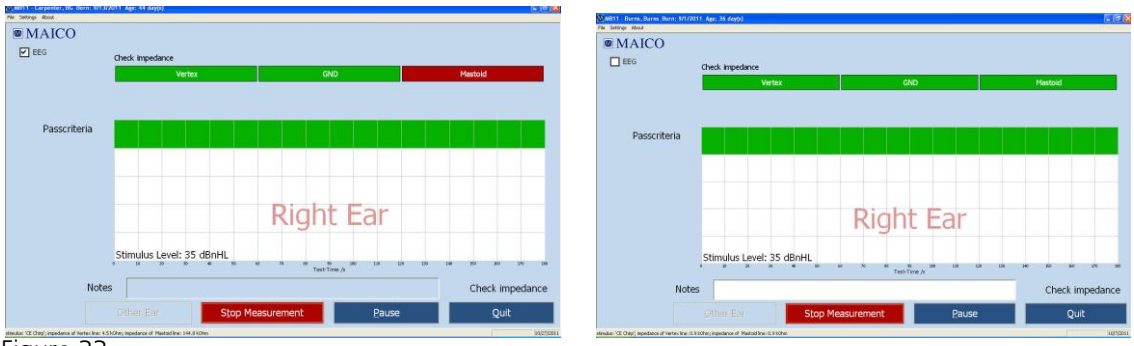


Figure 33
Impedance traffic lights at top of measurement window

The impedance is the resistance between the measuring electrodes (Vertex and Nape and the ground electrode. This impedance is influenced by the resistance of the electrodes and the resistance of the skin. The impedance should be in the range of 250 Ohm to 15.000 Ohm for each electrode reading. Impedance in this range will allow the best EEG quality.

The top of the test screen shows the impedance traffic light (Figure 33). Here the tester can see easily the status of the impedance test for each of the three electrodes. The green color symbolizes good impedance, yellow means not optimal and red signals poor impedance.

The impedance values measured for Vertex / Ground and Nape / Ground lines are shown in the status line in the lower left corner at the screen.

In case of red light the impedance needs to be corrected. Check the connection of the electrode to this site, and, if necessary use additional skin preparation material to clean the site better.

In some cases it takes a few seconds until the electrode gel takes effect.

The impedance test is passed when all three electrodes show green or yellow for approximately 7 seconds. After passing the impedance test the measurement starts automatically and the impedance traffic light changes into the signal quality traffic light.

6.4.2 The signal quality control

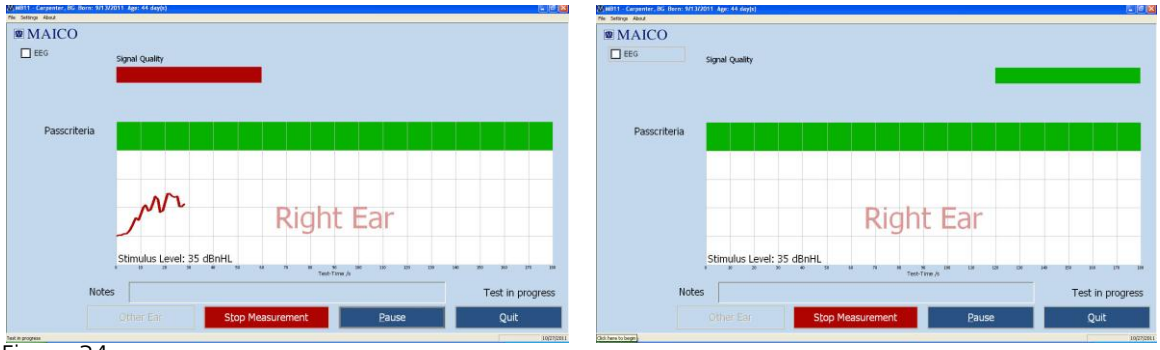


Figure 34
MB 11 - program test screen showing bad and good signal quality

The signal quality is determined by the ratio of artifacts versus accepted samples of EEG data. Artifacts are large potentials that are rejected during the recording. They can be caused by electrical noise in the environment, muscle activity related to movement of the baby, muscle tension or loss of acceptable electrode impedance. Excessive periods of artifact can prolong the test time and may increase the chance of a "Refer" result.

After the impedance test is completed and data collection begins, the signal quality light is displayed at the top of the test screen. Red indicates poor recording quality (artifact), yellow indicates fair quality and green indicates good signal quality. When the signal quality meets conditions to display a yellow or green bar, the test proceeds. When the signal quality is poor (red light) then artifacts are occurring which, in effect, pauses data collection.

The signal quality indicator light on the MB 11 Classic amplifier box also shows a color indicator of signal quality that matches the display on the screen.

If the signal quality remains poor for a prolonged period, check the contact of the electrodes to the skin. If poor signal quality is caused by movements from the baby and muscle artifact, the test will continue automatically as soon as the baby is calm and the signal quality is good again. If necessary due to excessive agitation of the baby, consider manually pausing the data collection by pressing the "PAUSE" button and allow the baby to calm down before continuing the screening.

6.4.3 EEG-Display

The EEG display mode can be accessed by clicking on the "EEG" checkbox on the left of the test screen.

The EEG view at the top of the screen allows you to monitor the ongoing real-time EEG activity. The EEG in this view will be relatively flat when the baby and electrical conditions in the environment are quiet. When the baby becomes active you will note higher amplitude activity in the EEG representing myogenic activity from the baby. If there is electrical interference in the room you may note spikes of activity showing in the EEG. This may be improved by checking the placement of the electrodes on the baby's head. View of a rolling, cyclical waveform in the EEG can indicate that the electrode gel from two sites on the baby's head have merged. This can negatively affect the quality of the recording.

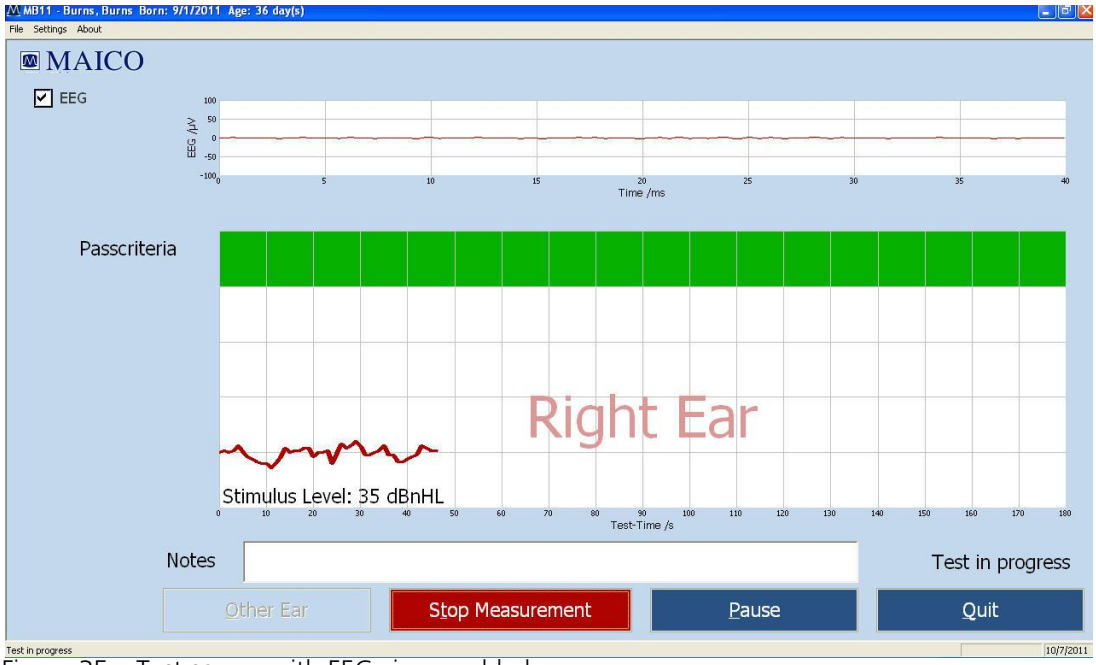


Figure 35 – Test screen with EEG view enabled

At the bottom of the test screen are several function buttons:

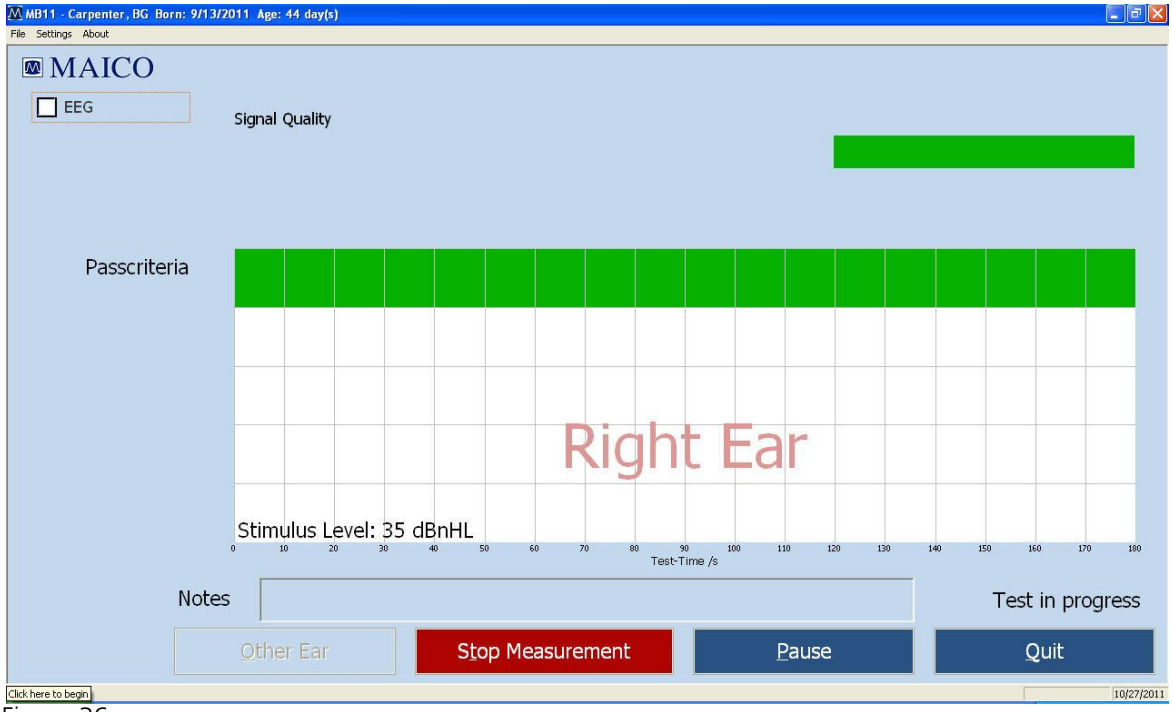


Figure 36
MB 11 - program "Test stop"

Other Ear: After the test is completed on one ear, use this button to change to the other ear. Then select "Start Measurement" when ready. Note that when an MB 11 Classic is attached to the PC, the Other ear button cycles through selections for Right ear, Left ear and Binaural (i.e. Both ears) tests if the Binaural testing setting is enabled in the Options dialog. Be sure that you cycle through to your desired ear measurement based on the ear(s) to which you have coupled the insert phones.

Start Measurement: Click on the "Start Measurement" button to begin a new test. The function button changes to "Stop Measurement".

Stop Measurement: An ongoing test can be aborted by clicking on the button "Stop Measurement". The result (Abort) will be displayed and stored in the database for quality- controlled tracking. If tracking is enabled, then a pop-up window will open allowing you to choose the reason for the test termination.

Pause: Stops the collection and processing of EEG samples although the acoustic stimulus continues to be presented. The function button changes to "Continue" and the status indication at the bottom of the screen shows "Test in progress". Select the "Continue" button to resume data processing.

Quit: Completes the screening phase and returns to the main screen.

EEG: Enabling the EEG checkbox replaces the signal quality indicator light with a display of ongoing EEG activity.

6.4.4 Test result "Pass"

Figure 37
MB 11-program "Test result PASS"

During the test, a small segment of a line is drawn after each 1 second of data collection. The line displays as blue for a left ear test and red for a right ear test. Progress toward reaching the criteria for a "Pass" result is indicated by the movement of the line upward toward the green area of the graph. When the line reaches the green area, a "PASS" result displays inside the green area. (see Figure 37).

When you leave the test screen by clicking on the button "QUIT" the test result will be stored automatically in the data base. Selecting Quit during active data collection will terminate the data collection with an Abort outcome.

6.4.5 Test result "Refer"

Figure 38
MB 11–program Test result "REFER"

If 100% of the pass criteria is not reached after 180 seconds of data collection time, the test is automatically terminated and a "REFER" will be displayed below and to the right of the graph.

In this case, follow your screening program protocol to determine whether another screening should be performed or whether the baby will be referred for a diagnostic follow-up test.

When you leave the test screen by clicking on the button "QUIT", the test result will be stored automatically in the data base.

Figure 39
Test result "Abort"

If the test is aborted by manual selection of the "Stop Measurement" button or the "Quit" button by the screener, the test will be documented as an Abort. If Tracking is enabled, a pop-up window will display to allow selection of a reason for termination. After confirming a reason, the result "Abort" with reason is shown in the green area (see Figure 39). When you leave the test screen by clicking on the button "QUIT", the test result will be stored automatically in the data base.

6.5 Binaural Screening

With the MB 11 Classic, simultaneous binaural testing is possible. This allows both ears to be screened at the same time. Testing will continue until both ears achieve a Pass result or until one or both ears' test terminates in a Refer result. To perform a "binaural" test, the setting **"Binaural Test Allowed"** in the Options dialog must be enabled. Otherwise the selection of Binaural in the ear button control will not be possible.

6.5.1 Preparing for a Binaural Screening

Prepare the patient as described in chapter 6 but apply the disposable ear tips or EarCups for both ears.

Select the "Ear" button on the Main window or the "Other Ear" on the measuring screen until "Binaural" (in pink letters) is displayed. Click on "Start Measurement" to begin measurement. The stimulus and the data collection will begin for both ears simultaneously.

6.5.2 Binaural Screening Result

Unlike monaural test, the binaural measurement will display two colored lines, red for the right ear and blue for the left. Both ears are screened for hearing loss at 35dBnHL. If responses are detected from both ears, the lines move upward until it reaches the 100% area colored green, then the result will be shown as "PASS".

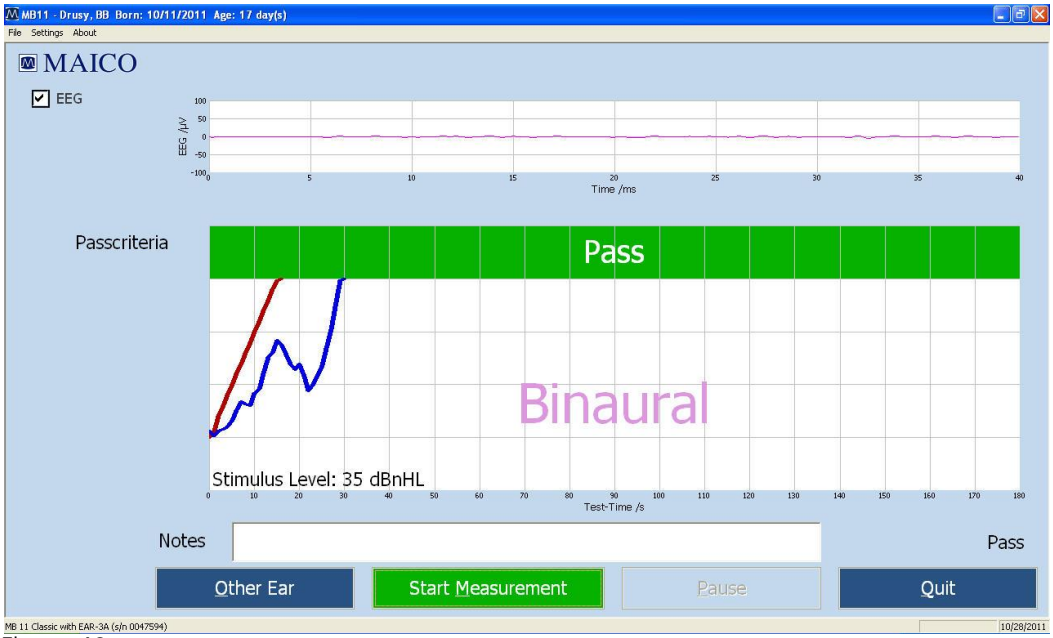


Figure 40
MB 11 – Binaural screening program Test result "PASS"

If no response is detected in one or both ears, the line for that ear will not reach the 100% green area after 180 seconds, the result will be "REFER".

NOTE: For Binaural Testing, a "PASS" result can only be obtained when the 100% pass criteria are reached by both ears. If either of the ears fails to reach the 100% pass criteria after three minutes, even if the other ear had reached the 100% pass criteria, the screening result will be shown and recorded in the database as "REFER" for proper follow-up actions (Figure 41).

Figure 41
MB 11–Binaural screening program Test result "REFER"

7 Tracking

The MB 11 software has an export function which allows export of patient and test data into files that are compatible with a few data management programs designed specifically to track newborn hearing screening information (HI*TRACK, OZ ESP or an ascii file).

7.1 Tracking Settings

Choose "**Settings**", Sub menu

"Options" (Figure 42)

The Options dialog opens and the tracking controls are:

Figure 42
Menu setting Options-access to Tracking

"No Tracking"- no tracking file will be saved.

"HI*TRACK" – A Tracking button will be added to the main screen. Selection of this button opens a window providing access to a wide variety of fields that are compatible with the HI*TRACK data management application. The entered information and test findings are saved in a file that can be exported into the HI*TRACK application. (see section 7.2)

"OZ Systems" – As data is collected the patient and test information is saved automatically in a file that can be exported into the OZ web-based data management system. .

Note: binaural tests collected with the MB 11 Classic hardware are not compatible with the OZ tracking system at this time. If you use OZ as your tracking database, perform only monaural tests with your MB 11.

"Tracking File Name" – To define the desired name for the tracking file.

"Tracking Path" - Here you can define the path for the tracking directory.

7.2 Input of Tracking data

If Settings/HI*TRACK is activated, the function button "Tracking" appears on the start screen:

Figure 43
Start screen with function button Tracking data

Click on the Tracking button to open the input window.

Patient data will be copied from the main screen.

Fill out the form with the information your program tracks. Click on the "advanced" button to open the next input window which contains additional fields as seen in Figure 44.

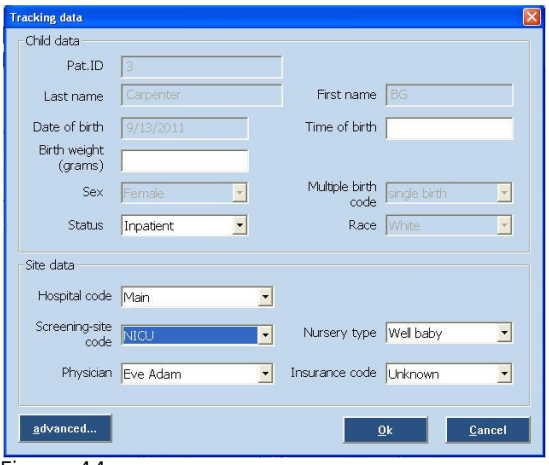


Figure 44
Tracking data

7.3 Advanced Tracking data

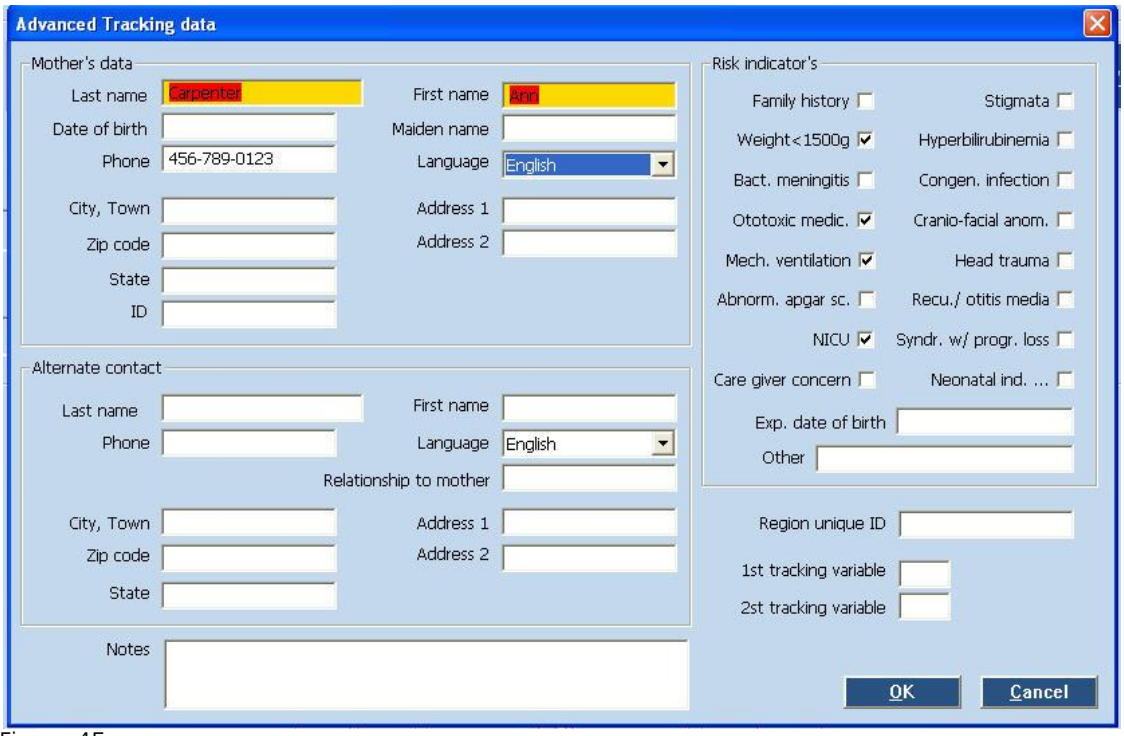


Figure 45
Advanced tracking data

The Advanced tracking dialog allows entry of Mother's data, an Alternate Contact's information as well as documentation of the relevant risk factors for the baby.

7.4 The export functions of the MB 11 database (no tracking enabled)

The MB 11 software allows the export of patient and test data from the database. The export file will be exported as text file (*.txt) in the Excel compatible CSV format. The CSV format allows easy import into Excel or other software.

To export the data, click "Search" on the start screen:

The "Load from Database"dialogue appears (Figure 46). Choose the data for export using the filter fields and set the date range in the Date Export area. Then click on the Export button appears. A browser dialog will open allowing you to type in the name of the export file and the location for storage. You can limit the list of exported data using the various search filters described in section 5.5.1.

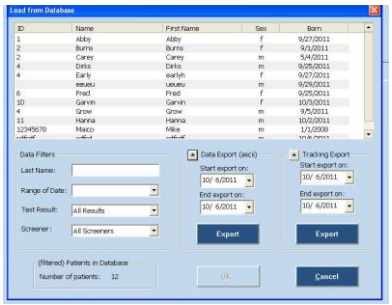


Figure 46
Load from Database

7.5 The export functions of the MB 11 database (Tracking enabled)

The MB 11 software allows the export of patient and test data from the database into an OZ or HiTrack compatible format. To do this, the OZ or HiTrack Tracking option must be enabled in the Settings/Tracking settings menu.

To export the data, click "Search" on the start screen:

The "Load from Database"dialogue appears (Figure 47). Choose the data for export using the filter fields, set the date range in the "Tracking Export" area and click the "Export" button in the Tracking Export area. A browser dialog will open allowing you to type in the name of the export file and the location for storage. Be sure that the filename and extension you enter here is the one that OZ or HiTrack will be looking for to merge the data. You can limit the list of exported data using the various search filters described in section 5.5.1.

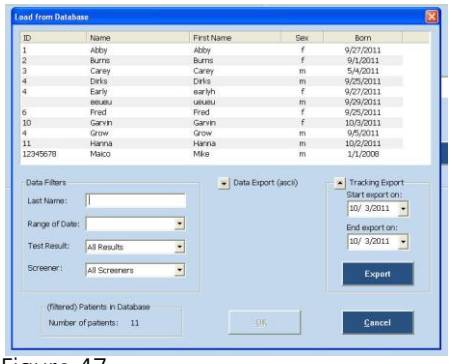


Figure 47
Load from Database

8 Technical Data

CE 0123

The MB 11 Classic is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Standards:	IEC 60601-1, IEC 645-3, IEC 645-7 Type 2
Test signals:	Screening: CE-Chirp Stimulus™
Stimulus rate:	Screening: 93/s
Stimulus intensity:	Screening: 35 dB nHL
EEG filter:	125 - 1250 Hz
Preamplifier:	Integrated, 87 dB amplification (23,000 x)
Sample rate:	16 kHz
Quality control:	Integrated indicator in Pre-amp unit and display in software with signal quality display or with EEG
Operation conditions:	+15 to +35 ℃ (+ 59 to + 95° F); max humidity 75%
Storage conditions:	+5 to +50 ℃ (+ 41 to + 122° F); max humidity 90%
Transducer:	ER-3A insert phones with EarCup adapter
Electrodes:	Disposable snap
Quality control:	Integrated indicator red (signal quality low), green (signal quality OK)
Weight:	300 g

Instrument
(MB 11 Box)

Power Supply:	via USB port of computer
Power Consumption:	max. 400 mA
Weight:	165 g
Dimensions:	W x D x H: 12 x 9 x 3 cm

Computer requirements (computer not included):

Type:	Intel Pentium III 800 MHz compatible or better
RAM:	minimal 256 MB RAM
Hard disk:	Minimal 2 GB
Interface:	USB 1.1 or 2
Display:	SVGA-Colour Display 800x600 or better
Operating system:	Windows 2000 SP 4, Windows XP SP 1 or later, Windows 7 Professional 32/64bit, Windows 8 Pro 32/64bit,

Mains supply:

Use only protective earth conductor plugs and wiring for the power supply. The lack of grounding will lead to enhanced humming noise with a large affect on the measurement quality. The buzzing noise also affects the audio output of computers and produces a masking noise signal. This will falsify the results of the measurements.

PC battery Mode:

To assure the most undisturbed (humming noise free) measurement and masking noise free stimuli it, is necessary to disconnect all external accessory PC devices, such as those with external power supply like USB Units, printers and local area network cables (LAN).

If it is necessary to use accessory devices while you operate in the battery mode, ensure a separate continuous and sufficient grounding of your PC.

9 Scientific Background Information

9.1 CE-Chirp Stimulus™

The stimulus for an automated ABR-newborn hearing screening should generate auditory evoked brainstem responses with an amplitude as great as possible at the level of 35 dB HL. High response amplitudes allow a fast objective detection with high specificity and short measuring time.

Up to now in the field of hearing screening the standard click was used as stimulus. The standard click is generated by delivering a short rectangular electrical impulse to a transducer. This click generates a traveling wave along the basilar membrane. The traveling wave runs from the basal part of the cochlea along the basilar membrane to the tip of the cochlea (apex). Hereby it excites each of the frequency areas of the cochlea starting with high frequency part and ending with the low frequency part. The velocity of the traveling wave is the greatest at the basal part of the cochlea and slows exponentially towards the apex.

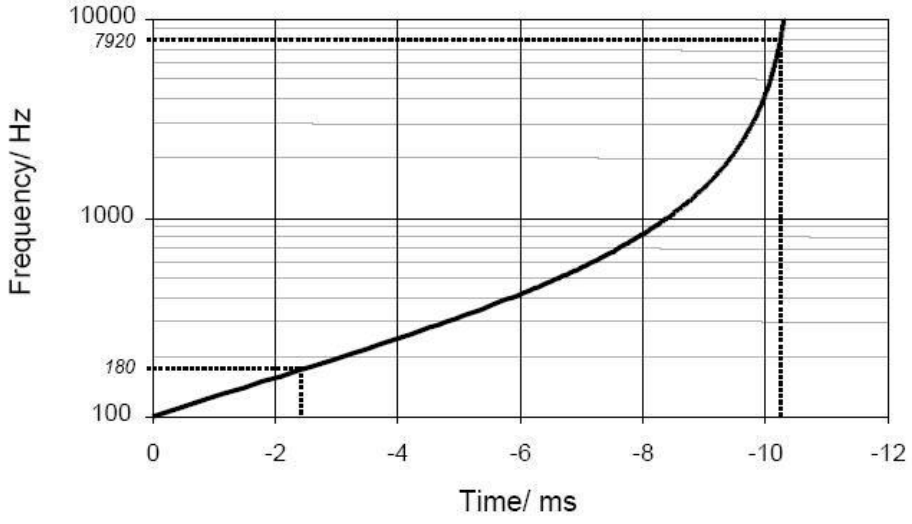


Figure 48

Figure 48 shows the delay of the travelling wave for reaching the various frequency bands in the cochlea calculated from the cochlea model of de Boer. The figure shows a delay shorter than 2 ms for the region from 10 kHz to 1 kHz but a delay of 8 ms from the area of 1 kHz to 100 Hz. Due to the resulting greater synchronization of excitation in the basal part of the cochlea, only the higher frequency range contributes effectively to the click-evoked activity. The traveling wave delay in the more apical part of the

cochlea is responsible for considerably dispersed responses from this area. For this reason, the spatio-temporally summated response does not achieve the amplitude that would result from a more synchronous excitation.

The new CE-Chirp Stimulus implemented in the MB 11 Classic allows a well synchronized activation of the whole cochlea.

In contrast to the conventional generation of a click in the time domain, in the frequency domain a click-like stimulus can be created through the addition of a large number of cosines with a fixed frequency difference. The frequency difference is selected in accordance with the desired stimulus repetition rate.

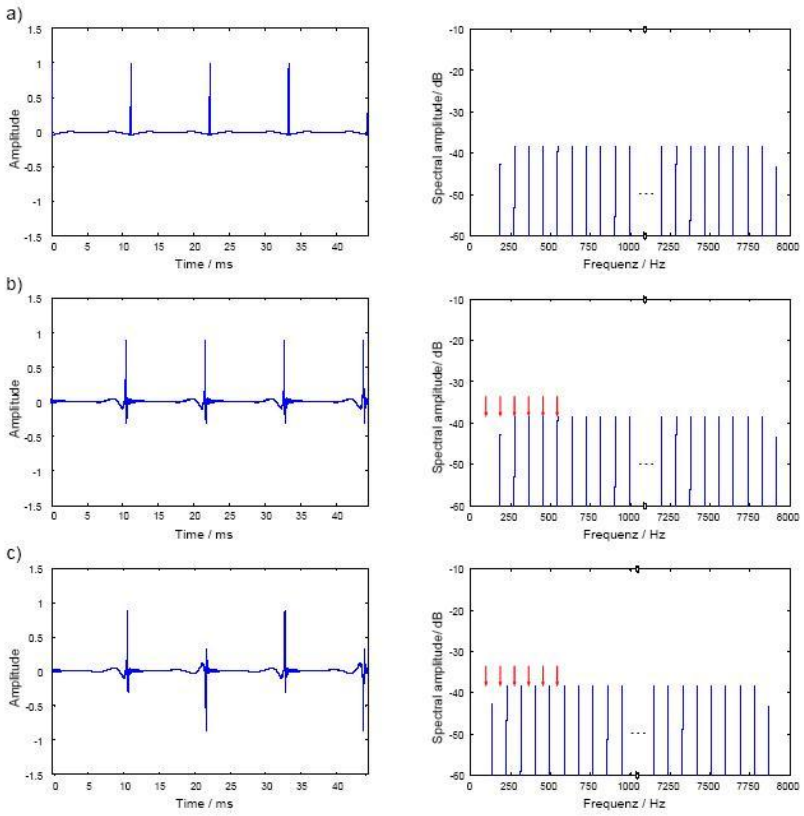


Figure 49

Figure 49 a) shows in the right panel the frequency spectrum of such a click. Every component of the spectrum represents a cosine. The difference between the single cosines is 90 Hz and is equal to the stimulation rate of 90 /s. A ripple between the individual pulses of the stimulus in the time domain shown in the left panel of Figure 49 a) can be effectively reduced by halving the amplitudes of the cosines with the lowest and the highest frequency. In contrast to the standard click generated in the time domain the new stimulus is a steady-state signal.

The patented stimulus constructed from individual cosines offers the possibility of introducing a frequency-dependent phase correction in order to compensate for the propagation time in the cochlea. From this phase correction a synchronized activation of the whole basilar membrane can be expected.

Figure 49 b) shows to the left the time course of a phase corrected click. The corresponding amplitude spectrum is shown at the right side. The red arrows mark the position of the first six spectral harmonics of the brainstem response evoked by the phase corrected stimulus. These harmonics were analyzed by the objective statistical test implemented in the automatic test algorithm of the MB 11 software. It is easy to see that five of the six harmonics of the brainstem responses are overlapping with the stimulus frequencies. This overlapping could lead to false results of the statistical test when electrical stimulus artifacts occur. For elimination of this source of error a frequency offset is introduced into the cosines. This frequency offset causes a displacement of the stimulus frequency spectrum. In the time domain, the frequency offset leads to an alternating stimulus. With this stimulus a better detection time and shorter test time could be realized.

For further optimization the question of the adequate cochlea model for calculating the phase correction was addressed. The cochlea model from de Boer is based on measurements at ears of dead bodies with non physiological high stimulus levels. Due to this fact the cochlea delay derived from the de Boer model has to be considered as not optimal. For this reason a new model function of the frequency-dependent propagation time in the cochlea was calculated based on the latency data of frequency specific ABR recorded at low stimulus levels.

In this context the question arises as to whether the delay of the different models has to be considered to reflect the group delay or the phase delay of the cochlea. The phase delay describes how much a steady-state cosine of a specific frequency is delayed from the input to the output of a system (of the cochlea). The group delay describes how much the envelope of a signal formed by a narrow group of frequencies is delayed through the system.

The results of a study confirmed the assumption that the latencies of the frequency-specific ABR reflect the group delay. Since the stimulus shall compensate for the cochlear delay of single frequencies the phase delay calculated from the group delay was used for the phase correction of the individual cosines of the stimulus. Figure 49 c) shows the time course of the resulting CE-Chirp™ Stimulus. For preventing an overlapping of response harmonics by electrical artifacts the above described frequency offset has to be added, too.

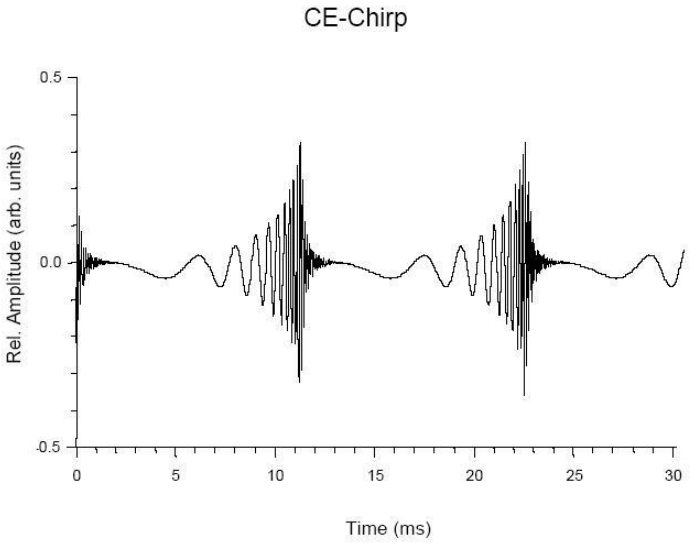


Figure 50

Extensive investigations on newborns have shown that the CE-Chirp™ Stimulus generates significant better results than other acoustical stimuli used for newborn hearing screening. At 35 dBnHL stimulus level, usually used for automatic ABR newborn hearing screening, we found a high specificity and short test time in newborns. The combination of the CE-Chirp™ and the Standard leads to very short examination times for newborn hearing screening.

Click-evoked ABR at high stimulus repetition rates for neonatal hearing screening
Stürzebecher E, Cebulla M and Neumann K. Int J Audiol, 42(2):59-70, 2003

10 Warranty, Maintenance and After-Sales Service

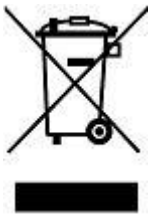
The MB 11 Classic ABR-Screener is guaranteed for 2 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

The MB 11 Classic may be repaired only by your dealer or by a service center recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument.

In order to ensure that your instrument works properly the MB 11 should be checked and calibrated at least once a year. This check must be performed by an authorized MAICO dealer.

When returning the instrument for repairs it is essential to send all the components.
Send the device to your dealer or to a service center authorized by your dealer. Please include a detailed description of faults.
In order to prevent damage in transit, please use the original packing if possible when returning the instrument.



The customer is committed to dispose of the delivered goods according to the rules stipulated by law. The costs for disposal have to be paid by the end-user.

11 Safety Regulations

14.1 Electrical Safety: The MB 11 Classic ABR-Screener is specified to comply with the international standard IEC 60601-1 (EN 60601-1).

The MAICO MB 11 is guaranteed according to IEC 60601-1 safety against electrical hazard only when the connected notebook computer is powered by batteries or the computers power supply accords to IEC 60601-1 or IEC 950-1 safety regulations.

The instruments are not intended for operation in areas with an explosion hazard.

14.2 Measuring security: To guarantee that the instrument works properly, it has to be checked at least once a year.

The service and calibration must be performed by an authorized service centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.

14.3 Device control: The user of the instrument should perform a subjective instrument check once a week. For your own security, you should copy the printout of the test and store it in your files.

14.4. User Instruction: The MAICO MB 11 Classic is designed to be used only by skilled personnel (Audiologists, physicians or other trained personnel. No person should attempt to use this instrument without the necessary knowledge and training to understand how this equipment is to be properly utilized.

Specifications are subject to change.

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